FEDERAL TRADE COMMISSION

I N D E X (PUBLIC RECORD)

EXHIBITS	FOR ID	IN EVID
Commission		
Number 52		1546
Schering		
None		
Upsher		
None		

OTHER EXHIBITS REFERENCED	PAGE
Commission	
None	
Schering	
None	
Upsher	
None	

FEDERAL TRADE COMMISSION

In the Matter of:	)
SCHERING-PLOUGH CORPORATION,	)
a corporation,	)
and	)
UPSHER-SMITH LABORATORIES,	) File No. D09297
a corporation,	)
and	)
AMERICAN HOME PRODUCTS,	)
a corporation.	)
----------	)

Friday, February 1, 2002

9:45 a.m.

TRIAL VOLUME 8

PART 1

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

Reported by: Susanne Bergling, RMR

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P R O C E E D I N G S

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JUDGE CHAPPELL: Good morning, everyone.

ALL COUNSEL: Good morning, Your Honor.

JUDGE CHAPPELL: We are going to reconvene docket 9297.

Complaint counsel, are you ready to call your next witness?

MS. BOKAT: Yes, I am, Your Honor.

JUDGE CHAPPELL: Is counsel for Andrx here?

MR. SHAFTEL: Your Honor, yes, if I could introduce myself for the record, Hal Shaftel from the Solomon Zauderer firm. I'm here both on behalf of Andrx and Mr. Rosenthal individually, who as I understand it will be the first witness today.

I don't know Your Honor's practices or protocol. To the extent we have concerns or objections as it relates I guess particularly to confidentiality or perhaps privilege issues, it would be my expectation to raise those objections with the Court.

JUDGE CHAPPELL: That's why I wanted to know if someone was here from Andrx. After the witness testifies, I'm going to review the transcript of the prior deposition, and I'm going to decide whether and what testimony is to be released to the respondents for

cross examination, and at that point, I will allow you, if you wish, to advise me that this information is classified or confidential or highly sensitive and that you expect to move for in camera treatment, and if I know that, under our new rule, 3.45 (g), I can grant provisional in camera status, meaning it will remain within the room, off the public record, and give you time to file a proper motion with a supporting affidavit.

MR. SHAFTEL: Very good, Judge, thank you.

JUDGE CHAPPELL: Thank you.

Anything else?

MR. CURRAN: No, Your Honor.

JUDGE CHAPPELL: You may proceed.

MS. BOKAT: Complaint counsel call Lawrence Rosenthal.

JUDGE CHAPPELL: Raise your right hand, please.

Whereupon--

LAWRENCE ROSENTHAL

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

JUDGE CHAPPELL: Thank you, have a seat.

State your full name for the record, please.

THE WITNESS: Lawrence Rosenthal.

DIRECT EXAMINATION

BY MS. BOKAT:

Q. Good morning, Mr. Rosenthal.

A. Good morning.

Q. By whom are you employed?

A. Andrx Pharmaceuticals.

Q. What is the business of Andrx Pharmaceuticals?

A. The manufacture and sale of generic drugs and branded drugs.

Q. How long have you been employed by Andrx Pharmaceuticals?

A. Approximately three years.

Q. So, was that beginning in 1999?

A. January of 1999.

Q. What is your position with Andrx Pharmaceuticals?

A. Vice president of sales and marketing.

Q. How long have you held the position of vice president of sales and marketing with Andrx?

A. Since I joined the company in January of 1999.

Q. Who is the senior marketing person at Andrx Pharmaceuticals?

A. I am.

Q. What are your responsibilities, sir?

A. Responsible for the sales and marketing of the generic product line, licensing of generic products,

business development issues.

Q. Could you describe your responsibilities for sales and marketing of generic pharmaceuticals?

A. Well, all of sales and marketing reports to me. I'm totally responsible for the bottom line of our generic sales.

Q. Are you responsible for the pricing of Andrx's generic pharmaceuticals?

A. Yes, I am.

Q. Prior to January 1999, were you employed by another pharmaceutical company?

A. Yes, I was employed by Teva Pharmaceuticals.

Q. At that time, what was the business of Teva Pharmaceuticals?

A. Primarily they were also a manufacturer and seller of generic pharmaceuticals, but they had a small branded component also.

Q. How long were you employed by Teva?

A. Twelve years, I believe, 12 or 13 years.

Q. So, was that beginning in about 1986?

A. I think, yeah, '86.

Q. What positions did you hold with Teva?

A. Director of sales administration, director of private label sales, director of sales, vice president of sales and marketing.

Q. What was your last position with Teva?
A. Vice president of sales and marketing.
Q. In that position, were you the senior marketing person at Teva?
A. Yes, I was.
Q. What were your responsibilities as the vice president of sales and marketing at Teva?
A. Similar to the ones at -- identical to the ones at Andrx basically.
Q. When you were with Teva, for how many generic products were you responsible?
A. I think we had approximately 100 products on the market.
Q. Typically, how is the first generic of a given branded product priced in relation to the branded product?
A. If it's the only generic on the market?
Q. Yes.
A. It's usually someplace between 30 and 40 percent discount to the brand, so 60 to 70 percent of the brand price.
Q. What happens to the brand price typically once a generic enters the market?
A. Brands tend to disregard generic entry as it regards price and tend to go on raising their prices on

an annual basis.

Q. Once a generic enters, what typically happens to the sales of the branded product?

A. They decrease.

Q. Why is that?

A. The generic achieves a certain substitution rate, and that substitution is taken from the branded -- directly from the branded product.

Q. Currently, what is the rate of generic substitution?

MR. CURRAN: Your Honor, I object on the grounds of foundation. This is not an expert witness. I think all of this testimony ought to relate specifically to this witness' personal experience.

MS. BOKAT: Well, this gentleman is responsible for the sales of all of Andrx's products. He was responsible for the sales of all of Teva's generics, which as he stated this morning, was approximately 100 products just at Teva. He has considerable experience with generic sales.

JUDGE CHAPPELL: I'll sustain the objection. I'll allow that line of questioning if you lay a proper foundation.

BY MS. BOKAT:

Q. Mr. Rosenthal, during your tenure at Teva and

Andrx, have you had occasion to monitor the sales of your company's products?

A. Yes, I have.

Q. Have you monitored the sales of the related branded products?

A. Yes, I see them. Yes, I do.

Q. Do you use any data to look at your sales and the related branded sales?

A. Yes, IMS data.

Q. Do you have occasion to look at sales of products in a therapeutic area if Andrx or Teva is considering introducing a product in the therapeutic area?

A. I have, but I tend mostly to look directly at the branded product that we would compete with.

Q. Mr. Rosenthal, currently, what is the rate of generic substitution?

A. Across the board or for all products?

Q. Yes.

MR. CURRAN: Objection, overbroad, Your Honor.

JUDGE CHAPPELL: I'll allow it if he knows the answer. If not, you're going to have to narrow it, Ms. Bokat. Overruled.

THE WITNESS: I believe generic substitution is -- approximately 45 percent of all prescriptions are

substituted generically.

BY MS. BOKAT:

Q. Do you monitor generic substitution rates over time?

A. I tend to look at individual generic products rather than the whole class of generics.

Q. Do you look at those individual products over time?

A. Yes.

Q. How long does it take for the generic substitution rate to arrive at the 45 percent?

A. Oh, 45 percent is an average of all the generic products, so -- of all the prescriptions written. So, individual products have different substitution rates.

Q. Is there a range among products in substitution rates?

A. Yes, there is.

Q. Can you tell me what the high and low end of the range are?

A. At what time period?

Q. Say six months after introduction of the generic.

A. I would say today they're approximately any place -- it's a broad range from 30 to I would say 80 percent at the end of six months, with most of them

falling into the higher range.

Q. Has that generic substitution rate changed over time?

A. I think it's -- yes, it has. It has increased over the last few years I've noted.

Q. How much increase have you noted over the last few years?

A. I think two years ago, you know, 60 percent at the end of six months would have been the high end. Now it's closer to 80 percent.

Q. That's 80 percent --

A. For certain drugs. Eighty percent of the brand's product is substituted at the end of six months.

Q. Do you know what is causing that increase in the substitution rate over the last few years?

A. I think it's a number of factors involved. One is the visibility of the drug, by that I mean how big a drug it is and how much visibility it has, so there have been some blockbuster drugs that have come off patent recently. Two is -- and not necessarily in order of importance, but I think there's a push by managed care to encourage generic usage to save money. I think those are the main factors. And also I think there's a greater acceptance by people to use generics

today than there was.

Q. In your experience, when the first generic of a given branded product comes to market, what percentage of the generic sales does that generic obtain?

A. I'm sorry, could you repeat that one?

Q. Sure, or I'll try it again, see if I can make it a little clearer.

Based on your experience, when a first generic comes on the market, a generic of a given branded product --

A. Right.

Q. -- what share of the generic sales does that generic get?

A. 100 percent.

Q. When a second generic comes on the market, what happens to the generic price?

A. It invariably declines.

Q. Why is that?

A. Because the second entrant usually tries to take market share through pricing.

Q. Once there's a second generic on the market, what happens to the price of the first generic?

A. It also declines.

Q. Once there's a second generic on the market, what happens to the sales volume of the first generic?

A. It declines.

JUDGE CHAPPELL: Mr. Rosenthal, could you speak up, please?

THE WITNESS: I'm sorry, it declines.

JUDGE CHAPPELL: Thank you.

BY MS. BOKAT:

Q. In your experience, is the profit margin on a generic drug related to how many generics there are in the market?

A. Yes, it is.

Q. What is that relation?

A. The more competitors, the smaller the profit margin.

Q. Are you familiar with the 180-day exclusivity period under Food and Drug Administration regulations?

A. Yes, I am.

Q. Can you explain to us what that is?

A. If someone challenges the patent of an innovator and is the first one to do so and is ultimately successful in their lawsuit, they are granted 180 days of marketing exclusivity.

Q. Does that exclusivity, the 180-day exclusivity, have any impact on the profit margin of the first generic?

A. Yes, they make more money, because there's no

competition during that period.

Q. Did Andrx Pharmaceuticals submit to the Food and Drug Administration an abbreviated new drug application for a generic of K-Dur 20?

A. Yes, they did.

Q. Do you know approximately when Andrx submitted that application?

A. I believe it was in March of 1999.

MS. BOKAT: Your Honor, I would like to show the witness an exhibit. This has not previously been admitted. I was going to ask the witness some questions about it and then offer it in evidence.

JUDGE CHAPPELL: Have the respondents seen the exhibit?

MS. BOKAT: I have copies for them here today. I gave them notice that I would be using it with this witness, and it's been on our exhibit list.

JUDGE CHAPPELL: Do you know if they're objecting to the admission of it?

MR. CURRAN: Can you identify the document, please?

MS. BOKAT: Certainly. This is CX 52.

MR. CURRAN: No objection, Your Honor for Upsher-Smith.

MR. LOUGHLIN: No objection, Your Honor.

JUDGE CHAPPELL: Are you offering it at this time?

MS. BOKAT: Then I would like to offer it in evidence at this time, please, CX 52 offered in evidence.

JUDGE CHAPPELL: CX 52 is admitted.

(Commission Exhibit Number 52 was admitted into evidence.)

JUDGE CHAPPELL: You may proceed.

MS. BOKAT: May I provide a copy to the witness?

JUDGE CHAPPELL: Yes, you may.

MS. BOKAT: Would you like a copy, Your Honor?

JUDGE CHAPPELL: I can see it, thanks.

Ms. Bokat, you might want to give one to Ms. Arthaud.

MS. BOKAT: Thank you, definitely.

Mr. Curran pointed out that this exhibit is a four-page document, so we will submit to the Court the remaining pages. I believe he said he has no objections if I go ahead and ask Mr. Rosenthal about this initial page?

MR. CURRAN: That's correct, Your Honor.

JUDGE CHAPPELL: Okay.

BY MS. BOKAT:

Q. Mr. Rosenthal, what is this document, CX 52?
A. It appears to be a covering letter to the FDA submitting a new drug application for Andrx's version of K-Dur, a generic potassium chloride extended release tablet, 10 mEq and 20 mEq.
Q. And was this sent by Andrx to the Food and Drug Administration on March 22nd, 1999?
A. Yes.
Q. Did Schering sue Andrx Pharmaceuticals for patent infringement related to K-Dur 20?
A. I believe they did, but I'm not 100 percent certain.
Q. I'm sorry, you believe they did?
A. Yes, but I'm not certain.
JUDGE CHAPPELL: Sir, you are going to have to speak up some so we can hear you.
THE WITNESS: I'm sorry.
JUDGE CHAPPELL: Thank you.
BY MS. BOKAT:
Q. Did the Food and Drug Administration raise some questions about Andrx's application for a generic of K-Dur 20?
A. Since this submission letter in March of 1999?
Q. Yes, sir.
A. I believe there's been certain issues raised by

the FDA, yes.

Q. Do you know which company was the first to file an abbreviated new drug application for a generic of K-Dur 20?

A. My belief, it's Upsher-Smith Laboratories.

Q. At some time, did you learn any information about whether a company would have a 180-day exclusivity period on the generic for K-Dur 20?

A. Yes, it became my understanding that Upsher-Smith would have 180-day exclusivity.

Q. How did you learn that?

A. I'm not sure of the source of that information.

Q. Are you aware of the patent litigation settlement between Schering-Plough and Upsher-Smith?

A. I'm vaguely aware of some of the details, but not -- you know, I've read some public domain stuff about it, but I don't know the -- every detail in the agreement.

Q. What do you know about the agreement?

A. The things I recall is that Schering-Plough paid Upsher-Smith $60 million, that they licensed some products to -- Upsher-Smith licensed some products to Schering-Plough, and I eventually learned that they had -- they would allow Upsher-Smith to begin marketing the product in September of 2001.

Q. When did you learn that the agreement would permit Upsher-Smith to market its product in September 2001?

A. In the spring or early summer of 2001, I first started hearing about it, is my best recollection, from various customers who told me that Upsher-Smith was telling them that they would have generic K-Dur on the market in September of 2001.

Q. Prior to the spring of 2001, did you have any information about when the agreement would permit Upsher-Smith to come to market with their generic of K-Dur 20?

A. I might have, but, you know, the date I recall definitely knowing is, as I said, the spring or summer. I might have heard it prior to that, but I'm not sure.

Q. What does Upsher-Smith's 180-day exclusivity period on their generic of K-Dur 20 mean for Andrx's introduction of their generic?

A. It means Andrx won't be able to market its version until Upsher-Smith's exclusivity has expired.

Q. Back in 1999, did you know when the agreement between Schering and Upsher-Smith would permit Upsher-Smith to bring its generic to market?

A. I don't believe I did in 1999.

Q. Was that lack of information about when Upsher

could come to market a factor in prioritizing development products -- excuse me, development projects at Andrx, including your generic of K-Dur 20?

MR. CURRAN: Objection, leading, Your Honor.

JUDGE CHAPPELL: Sustained.

BY MS. BOKAT:

Q. Did your information about when Upsher could come to market have any impact on the development of Andrx's products?

MR. CURRAN: Objection, foundation, Your Honor. The witness has already testified he didn't know about the settlement between Upsher and Schering until spring or early summer of 2001.

MS. BOKAT: Your Honor, I don't believe that's his testimony. I believe his testimony was that it wasn't until the spring of 2001 --

MR. CURRAN: Correct, I stand corrected.

MS. BOKAT: -- that he understood Upsher would be able to come to market in September. I think his testimony was that in 1999, he wasn't informed of when the agreement would permit Upsher to come to market.

JUDGE CHAPPELL: Well, he has testified that he's aware of it, and the question didn't limit in time whether it affected Andrx products, so I'm overruling the objection.

Do you need the reporter to read the question back?

THE WITNESS: Please.

MR. CURRAN: Thank you, Your Honor.

(The record was read as follows:)

"QUESTION: Did your information about when Upsher could come to market have any impact on the development of Andrx's products?"

THE WITNESS: I would say that we prioritized products in a manner which the products that have the best sales potential and the least impediments toward getting to market receive priority.

BY MS. BOKAT:

Q. So, did your information about when Upsher-Smith would come to market have any impact on the priority for your generic of K-Dur 20?

A. Oh, I think once we learned that Upsher-Smith had exclusivity, that product took less of a priority.

MS. BOKAT: Your Honor, I'm about to ask Mr. Rosenthal a question that I believe may be commercially sensitive to Andrx Pharmaceuticals. I didn't want to simply ask the question, have the witness answer before Mr. Shaftel had an opportunity to say something. I don't know the best way to proceed, whether I should simply ask the question, ask the witness to wait on his

answer to see if Mr. Shaftel wants to say anything to the Court.

JUDGE CHAPPELL: Does the question involve documents which have been granted in camera treatment?

MS. BOKAT: It's not related to documents, Your Honor. It's just based on Mr. Rosenthal's information.

JUDGE CHAPPELL: Why don't you confide in Mr. Shaftel what you're going to ask and let him decide.

MS. BOKAT: May I have a moment?

JUDGE CHAPPELL: I don't have enough to rule one way or the other right now, and I can't do a preemptive clearing of the courtroom. So, go ahead and take a moment.

MS. BOKAT: Thank you.

(Counsel conferring.)

MS. BOKAT: Luckily, Your Honor, Andrx doesn't have any problems with my asking the question, so I'll go ahead and ask it. I don't think there's any need to clear the courtroom for this question and answer.

JUDGE CHAPPELL: Okay, just be advised, Ms. Bokat, there are a number of Andrx documents which have been granted in camera, so if you get into those, let me know.

MS. BOKAT: Thank you, I will.

JUDGE CHAPPELL: You may proceed.

BY MS. BOKAT:

Q. Mr. Rosenthal, does Andrx have approval from the Food and Drug Administration for its generic equivalent of K-Dur 20?

A. No, it does not.

Q. I'm going to shift topics on you for a minute and ask a series of questions about expiration dates.

Are there expiration dates for potassium chloride tablets?

A. There are -- yes, there are.

Q. How long do potassium chloride tablets have before they reach their expiration date?

A. It would depend on the individual product, the individual formulation, whose product it was, how much -- how much realtime stability data the people had on their product.

Q. Let me ask it in terms, then, of just the 20 milliequivalent tablets.

A. You're asking me Andrx's version or someone else's version?

Q. Let me ask you first Andrx's version. What's the shelf life on Andrx's generic of K-Dur 20?

A. I believe when approved it will be 24 months.

Q. Do you have any information about the expiration dates of other companies' 20 milliequivalent

potassium chloride tablets?

A. No, I don't.

Q. In order for Andrx to sell its potassium chloride 20 milliequivalent for full price, how much time needs to be left before the expiration date?

A. Usually you need 12 months of dating left on the product if you're to obtain full price in the marketplace.

Q. Now I'm going to shift topics again and ask about Andrx's generics generally.

When an Andrx generic is the first generic on the market, what product does it typically take sales from?

A. Well, it typically takes sales from the branded product for which it's a generic substitute.

Q. Why is that?

A. Because that's what it's -- that's what it's A-B rated to, bioequivalent to.

Q. And why is the A-B rating a factor?

A. Well, the A-B rating is a factor in substitution, that it can be legally substituted, and most states require an A-B rating to substitute a generic product.

Q. Have you considered what products Andrx's 20 milliequivalent potassium chloride product will take

sales from?

A. I believe it will take sales from K-Dur, it will take sales from Upsher-Smith's generic version, it will take sales from Warrick's generic version. It may or may not affect other potassium chloride drugs in the class.

Q. To what extent do you expect your generic of K-Dur 20 to affect other potassium chloride products beyond the 20 milliequivalent tablets?

A. I don't know. I haven't given it much thought.

Q. Why is it that you haven't thought about that?

A. Well, historically, from a generic perspective, we concentrate on substituting our product against the brand. You know, whether or not there is movement in other drugs within that class, within that same class of compounds, I don't think there's really ever been any good, definitive studies one way or another if there's an effect.

Q. So, do your generics usually take sales primarily from the referenced brand product and other generics of that branded product?

A. Primarily, yes.

Q. Do you have data available to you on sales of potassium chloride supplements?

A. On all potassium -- do I have data available to

me? Yes, I have data available to me.

Q. What data do you have?

A. I have IMS data.

Q. How long -- or let me ask first, have you been monitoring potassium chloride sales through the IMS data?

A. I haven't been monitoring it on a regular basis.

Q. Have you looked at IMS data of potassium chloride supplements?

A. Yes, I have.

Q. For what period have you looked at data?

A. I recently looked at the data on K-Dur, the generic from Upsher-Smith and the generic from Warrick over the last few weeks, from September through December I believe.

Q. Did that data give you information on the market share of K-Dur 20 since September 2001?

MR. CURRAN: Your Honor, I object. This is an attempt to make this witness into an expert witness without providing reports and an opportunity for deposition and so forth. This witness has already testified that he's -- he has not sold potassium chloride, he hasn't monitored potassium chloride sales, and he's simply someone who has reviewed some IMS data

recently after he was deposed by us as a fact witness in this case.

MS. BOKAT: Your Honor, this witness is vice president of sales and marketing for Andrx. He's responsible for sales of their products, and they have a 20 milliequivalent potassium chloride supplement in development. So, naturally he has looked at this IMS data set that he said that he recently -- routinely has available to him to see what's happening with potassium chloride sales in the 20 milliequivalent dosage strength.

JUDGE CHAPPELL: On your witness list, is Mr. Rosenthal listed as a fact witness or as an expert witness?

MS. BOKAT: He is listed as a fact witness.

JUDGE CHAPPELL: The objection is sustained.

MR. CURRAN: Thank you, Your Honor.

BY MS. BOKAT:

Q. Mr. Rosenthal, have you sought any information about the pricing of Upsher's generic of K-Dur 20?

A. Have I seen it?

Q. Have you sought any?

A. Oh, sought. Yes, I have.

Q. How did you seek that information about Upsher's pricing?

A. I called a number of their customers and asked them what they were paying for the Upsher product.

Q. What kinds of customers did you contact?

A. Primarily large chains.

Q. Were these retail drug chains?

A. Yes.

Q. What did they report about what they were paying for Upsher-Smith's generic?

MR. CURRAN: Objection, Your Honor, calls for hearsay.

JUDGE CHAPPELL: Basis? What's your basis for offering this?

MS. BOKAT: Again, Mr. Rosenthal is responsible for the pricing of Andrx's products. As part of his function, he needs to monitor pricing of other products so he can determine where they're going to price their own.

MR. CURRAN: Your Honor, it does appear that it's being offered for the truth of the matter asserted. There are better, more reliable sources of Upsher-Smith's pricing rather than what customers informally told this fact witness.

JUDGE CHAPPELL: I'll allow you -- I'll overrule it to the extent you can get into what pricing information, what pricing was given, but I don't want

to get into an extended examination of conversations. And I will allow you to get into the reliability issue on cross.

MR. CURRAN: Thank you, Your Honor.

JUDGE CHAPPELL: You may proceed.

BY MS. BOKAT:

Q. Mr. Rosenthal, what is your understanding of Upsher's pricing for their generic of K-Dur 20?

A. It's approximately 50 percent discount to the brand, in that area.

MS. BOKAT: Your Honor, could I have just a minute to confer with my colleagues, and maybe I can wrap up my direct?

JUDGE CHAPPELL: Yes, you may.

MS. BOKAT: Thank you.

(Counsel conferring.)

MS. BOKAT: Thank you, Your Honor.

BY MS. BOKAT:

Q. Mr. Rosenthal, you mentioned a range of generic substitution, I think it was between about 30 and 80 percent. What drugs usually are at that high end of the range, the 80 percent?

A. Well, it's easy to answer what drugs are at the low end of the range, actually.

Q. Okay.

A. The low end of the range tends to be drugs that are called NTIs or narrow therapeutic index drugs. They'd be drugs that doctors and pharmacists don't feel comfortable that the generic is going to perform exactly equivalent to the brand, and they would be in more critical areas of medicine, such as seizure medication or blood thinners, like warfrin and things like that. There's a list of about seven to ten drugs that comprise that list of NTIs. The rest of the drugs tend to, you know, tend to go towards the higher end, and that's in the, you know, the 60 to 80 part of that range.

Q. Are potassium chloride supplements a narrow therapeutic index drug?

A. No, they're not.

Q. I believe you testified in answer to one of my questions that once you knew Upsher had exclusivity, your generic for K-Dur 20 had less priority. I wanted to make sure that we were both talking about the 180-day exclusivity. Is that correct?

A. I'm sorry, could you repeat that whole question one more time?

Q. Sure.

When you were talking earlier this morning about Andrx's generic of K-Dur 20 taking a lesser

priority once you knew that Upsher had exclusivity, I wanted to make sure that when you had said "exclusivity," you were talking about the 180-day exclusivity.

A. Yes, I was.

MS. BOKAT: That concludes our direct examination, Your Honor. Thank you.

JUDGE CHAPPELL: Do respondents wish to begin their cross or do you want to wait until my ruling on the release of information?

MR. CURRAN: I would prefer to wait until I know what I have to work with, Your Honor.

JUDGE CHAPPELL: Okay.

MR. LOUGHLIN: Yes, also, Your Honor.

JUDGE CHAPPELL: Okay, I am going to take probably an hour. I would say less, but I don't want everybody to have to come in here early. I've got -- I'm going to review the deposition transcript. When I come back, to the extent any information is going to be produced, I'm going to go over page numbers and line numbers. So, Mr. Shaftel and Ms. Bokat, you need to have a copy in front of you when I make my ruling.

MR. SHAFTEL: Your Honor, if I could briefly be heard on the subject?

Andrx has filed a submission in which I think

we present very well-grounded arguments that Your Honor need not get so far as to review Mr. Rosenthal's prior testimony. Essentially there are two points.

One, that was a transcript given in an unrelated matter involving a different product, involving different facts and circumstances. The testimony was given in reliance on the confidentiality order in place in that proceeding. No party to that proceeding ever moved to claim that it was inappropriately classified or designated as confidential.

Apart from that and probably even more fundamentally, the Jencks Act, which I don't believe as a technical matter applies to this proceeding, to the extent the principle does, it is not to the exclusion of other principles, and this is not a case where the respondents have not had an opportunity to get prior statements from this witness.

To the contrary, Mr. Rosenthal appeared for a deposition. It was a full day deposition, he answered every question that was put to him, there was no motion brought to Your Honor to compel additional testimony. With respect to the facts and circumstances as this witness knows them relative to this case, there already has been a full opportunity, which respondents have

availed themselves of, to get whatever statements they wanted from Mr. Rosenthal.

This is not surprise testimony. There was a five-hour deposition. And I believe that very much distinguishes this scenario from one in which there was a surprise witness, prior statements were not provided. This is -- this is multiple bites at the apple without any showing that these prior statements have any bearing on this matter, and it's at least our view, enough is enough. They have had a deposition of the witness. They ought to be able to proceed on that basis.

JUDGE CHAPPELL: Victoria, would you come here, please.

(Discussion off the record.)

JUDGE CHAPPELL: Mr. Shaftel, I know you weren't here, but I've already ruled on this issue, and I instructed complaint counsel to inform you of that. Were you not told of my ruling?

MR. SHAFTEL: There may have been a miscommunication. I obviously would not have revisited the issue if I had appreciated that the subject had already been ruled on.

JUDGE CHAPPELL: Well, I understand your arguments and I'll consider them, but these statements

are in the custody of the Government, and the Commission has previously held that Jencks does apply -- just so you know, I'll reiterate my ruling earlier -- and I am going to apply Jencks, and I am going to review that deposition transcript, and I will be back with my ruling.

We will reconvene at 11:30. Thank you.

(A brief recess was taken.)

JUDGE CHAPPELL: Back on the record, docket 9297.

The Jencks Act, which is codified at 18 USC Section 3500, requires the Government to produce statements made by a government witness which relates to the subject matter as to which the witness has testified. I'm citing that in part.

The Commission, in the Balfour case, has agreed that Jencks applies to Commission proceedings. My standard will be, as the Jencks Act states, I'm going to require production of information related to the testimony, not any statement in the file of the Government.

Based on the testimony this morning, I have reviewed in camera the deposition of Larry Rosenthal taken on October 30th, 2000. I'm going to read by page number and line number the information which shall be

produced. If a page number and line number is not read, that means it's redacted.

The following information shall be released or produced to the respondents following a short recess:

Page 3, line 22, ending on page 6, line 11; page 6, line 23, ending on page 7, line 18; page 8, line 2, ending on page 11, line 18; page 25, line 19, ending page 26, line 17; page 32, line 7, ending page 32, line 9; page 45, that's 4-5, line 1, ending page 45, line 12; page 48, line 4, ending page 50, line 8; page 67, line 4, ending page 68, line 19; page 119, line 20, ending page 120, line 8; page 120, line 25, ending page 121, line 21; page 146, line 6, ending page 148, line 2; page 150, line 2, ending page 152, line 22. The remainder of the transcript shall be redacted.

At this time, we have to decide how to proceed. Mr. Shaftel, how long do you need to do a quick review to determine if you think any of that information will need to be treated as in camera?

MR. SHAFTEL: Your Honor, I believe I can do it within 30 minutes.

JUDGE CHAPPELL: Are you going to need to consult with anyone who's not here?

MR. SHAFTEL: There is a possibility of that, which is why I extended it out to 30 minutes.

JUDGE CHAPPELL: Why don't you take five or ten minutes, flip through that -- you followed along with me, did you not?

MR. SHAFTEL: Yes, Judge.

JUDGE CHAPPELL: If you see one thing that you think will -- you will be requesting in camera treatment for, that's what I need to know at this point. I just need to know if you -- just look at it quickly and let me know if you see something that you suspect will need to be treated in camera.

MR. SHAFTEL: Fine.

JUDGE CHAPPELL: So, we are going to take a break off the record, because I need to wait to hear from you, Mr. Shaftel, before I order the information to be turned over to respondents.

While we're taking the short break, though, I instruct complaint counsel to have a copy of that transcript prepared and redacted as soon as possible, including right now, beginning now.

MS. BOKAT: Right.

JUDGE CHAPPELL: So, we are going to take a break. We will go off the record for about five or ten minutes. Let me know when you're ready, Mr. Shaftel.

MR. SHAFTEL: Fine, thank you.

(A brief recess was taken.)

JUDGE CHAPPELL: Mr. Shaftel, have you had time to go over the information?

MR. SHAFTEL: Yes, Your Honor, thank you for your patience. There are three entries --

JUDGE CHAPPELL: Step up to the microphone. Now, I'm not entertaining a motion for in camera treatment, a formal motion. I'm just looking for whether there is material that you will request in camera treatment of.

MR. SHAFTEL: Your Honor, there are three entries from those that you identified that it would be our intention to make that application to the Court. Pages 67 -- beginning at line 67, line 4, through page 68, line 19.

I also would note for the record that at that entry and perhaps one or two others, documents are being described or discussed in the testimony, and at least I'm unclear whether or not the exhibits which are being addressed at those portions are anticipated to be turned over --

JUDGE CHAPPELL: No. No, the exhibits -- some of the -- some of the Q&A lines I included just for context, but the exhibits that are referred to are not being produced. To the extent they are self-explanatory, that's okay, but they are not being

produced.

MR. SHAFTEL: I don't know if the Court wants to hear my basis for my concerns at this point or should I just identify the list?

JUDGE CHAPPELL: You can do that in writing later.

MR. SHAFTEL: Okay. The entry beginning at page 146, line 6 through 148, line 2, and lastly, the very last entry beginning at page 150, line 2, through page 152, line 22.

JUDGE CHAPPELL: What was the last line?

MR. SHAFTEL: Page 152, line 22.

JUDGE CHAPPELL: Okay, based on Mr. Shaftel's representations to the Court, under Rule 3.45(g), I'm granting provisional in camera treatment to the entire -- the entire testimony, which I'm ordering the Government to produce today, so that in case you missed something, I forced you to look at it rather quickly, I'm provisionally granting this so that you can look over it in due time and you can decide whether you want to request in camera treatment for any of the information which I have ordered produced, but it will be treated as in camera for 20 days, and I think you and your firm, you're very much aware of the rules required for in camera treatment. Is that

right?

MR. SHAFTEL: Yes, Your Honor.

JUDGE CHAPPELL: So, I will be looking for that motion pretty quickly.

MR. SHAFTEL: Understood. Thank you.

JUDGE CHAPPELL: That's all for now.

Ms. Bokat, when do you expect to have the information ready to produce?

MS. BOKAT: One minute, Your Honor.

JUDGE CHAPPELL: Okay.

(Counsel conferring.)

MS. BOKAT: We're trying to get an answer to your question, Your Honor.

JUDGE CHAPPELL: Okay, you understand, I'm not expecting anything fancy here.

MS. BOKAT: Right. We haven't been able to -- we're still on the record?

JUDGE CHAPPELL: Yes.

MS. BOKAT: We haven't been able to track down the person I sent to make those copies as quickly as possible. So, we haven't been able to say don't make it fancy or get an answer on how long this process is going to take. I apologize to the Court.

JUDGE CHAPPELL: See, I wanted to include our lunch break in the time I give respondents to look over

the information, but I can't make a judgment on that until I know when they're going to have it in their hands.

Why don't we go ahead and go off the record.

(A brief recess was taken.)

JUDGE CHAPPELL: Let's go back on the record.

MS. BOKAT: The copies to be turned over to respondents' counsel should be ready to be turned over within approximately five minutes.

JUDGE CHAPPELL: Okay, five minutes.

Let's go back off the record. We'll take another break.

(Discussion off the record.)

JUDGE CHAPPELL: Let's go back on the record.

Okay, Ms. Bokat, it's my understanding that the copies of the documentation or information to be produced are going to be provided to the respondents very shortly. Is that correct?

MS. BOKAT: That is my understanding.

JUDGE CHAPPELL: And I want to give them time to review that information in preparation for their cross exam of Mr. Rosenthal, so we'll take an extended lunch break. It's about 12:25 now. We will take a break until 2:00, at which time the cross examination will begin.

We're in recess.

(Whereupon, at 12:25 p.m., a lunch recess was taken.)

AFTERNOON SESSION

(2:00 p.m.)

JUDGE CHAPPELL: Good afternoon, everyone.

ALL COUNSEL: Good afternoon, Your Honor.

JUDGE CHAPPELL: Back on the record, docket 9297.

Respondents, were you provided a copy of the excerpts from the deposition transcript of Mr. Rosenthal?

MR. CURRAN: We were, Your Honor, in a timely fashion.

JUDGE CHAPPELL: Have you had appropriate opportunity to review that information?

MR. CURRAN: Yes, Your Honor.

JUDGE CHAPPELL: Schering?

MR. LOUGHLIN: Yes, we have, Your Honor. We have, Your Honor.

JUDGE CHAPPELL: Okay. I don't believe we want to make the entire cross exam in camera, but remember that the portion you were given has been granted provisional in camera, so when you move into that or any of the other in camera exhibits during your cross examination, I need to know, okay?

MR. LOUGHLIN: Yes, Your Honor.

JUDGE CHAPPELL: With that, Mr. Rosenthal, we

need you to take the stand again. I remind you, sir, you're still under oath.

Who's going to go first?

MR. CURRAN: That's me, Your Honor.

JUDGE CHAPPELL: Mr. Curran, you may proceed.

CROSS EXAMINATION

BY MR. CURRAN:

Q. Good afternoon, Mr. Rosenthal.

A. Good afternoon.

Q. Mr. Rosenthal, Andrx is principally a generic pharmaceutical company, correct?

A. At this point, yes.

Q. And you're the vice president of sales and marketing?

A. Correct, for the generic division.

Q. For the generic division. So, you're responsible for sales and marketing on the generic side of Andrx, correct?

A. That's correct.

Q. Sir, generic pharmaceutical companies like Andrx bring to market lower cost alternatives to branded pharmaceutical products, correct?

A. Correct.

JUDGE CHAPPELL: Mr. Rosenthal, I'm going to need you to lean over towards the mike and speak up,

please.

THE WITNESS: Okay.

BY MR. CURRAN:

Q. So, sir, generic pharmaceutical companies make available to consumers lower cost alternatives, correct?

A. Correct.

Q. So, in a sense, generic companies like Andrx help consumers, correct?

A. We like to think so, yes.

Q. Sir, on your direct examination, you testified that you were generally familiar with the terms of the Hatch-Waxman Act, correct?

A. Yes.

Q. I'd like to discuss those terms and flesh out your understanding of that legislation, if I may.

Sir, you're aware that when a generic drug company files an ANDA, if there's a patent involved, it's required to give a Paragraph IV certification?

A. I'm aware of that, yes.

Q. At Andrx and at Teva, those companies have done that during your employ, correct?

A. Yes.

JUDGE CHAPPELL: Mr. Curran, I am going to need you to speak up, also.

MR. CURRAN: Yes, Your Honor.

BY MR. CURRAN:

Q. Sir, when a generic company gives a Paragraph IV certification, that goes to the brand name company, correct?

A. Yes.

Q. And the brand name company, under the Hatch-Waxman Act, has a period of time in which it may bring a patent infringement suit against a generic company, correct?

A. Correct.

Q. It's 45 days, correct?

A. Correct. Well, I believe they can bring suit after that, but they can't slow down the introduction of the drug. They can bring suit any time is my understanding.

Q. Very good. If they bring an action within that 45-day period, then under the Hatch-Waxman Act, there's a 30-month stay before the FDA can approve the generic alternative, correct?

A. That's correct.

Q. So, if a generic company files an ANDA, gives Paragraph IV certification to the brand name company and gets sued, it's barred from the market for 30 months, correct? Is that your understanding?

A. I thought it was 30 months or a final court decision, whichever came first is my understanding.

Q. Okay, very good. So, if it's -- if it's -- after 30 months or an earlier final court resolution, correct?

A. Correct.

Q. Sir, during your employment at Andrx, have you ever been precluded from bringing a drug to market because of that 30-month stay?

A. Yes, we have.

Q. Numerous times, correct?

A. Yes.

Q. Now, sir, sometimes patent infringement litigation keeps a generic off the market even after that 30-month period, correct?

A. That's correct.

Q. Not as a matter of law, right?

A. Correct.

Q. But as a matter of practical reality, it keeps the generic company off the market, right?

A. That's correct.

Q. Andrx has a situation just like that right now, doesn't it?

A. Yes, it does.

Q. We're talking about the Prilosec situation?

A. Yes, I am.

Q. Sir, in 1998, Andrx filed an ANDA to introduce a generic version to Prilosec, correct?

MS. BOKAT: Objection, Your Honor. I think this is well beyond the scope of the direct examination. We didn't go into this Prilosec drug at all.

MR. CURRAN: Your Honor, as will become apparent, the effect of the Hatch-Waxman Act upon a generic company like Andrx bears directly on the predicament that Upsher-Smith faced in 1997 at the time of the settlement, and to corroborate the testimony of the Upsher-Smith witnesses, I want to elicit from this witness information indicating how the Hatch-Waxman Act works in reality and in practice.

JUDGE CHAPPELL: I can't read the question, because my CaseView has gone out, but Court Reporter, would you repeat the question for me, please, before the objection?

(The record was read as follows:)

"QUESTION: Sir, in 1998, Andrx filed an ANDA to introduce a generic version to Prilosec, correct?"

JUDGE CHAPPELL: I recall the witness was asked about a 180-day rule during his direct, is that right, the exclusivity period?

MS. BOKAT: Right, but I think this is a different exclusivity period that Mr. Curran is going into. This is not the 180-day period now. He's into a separate provision about a 30-month period.

MR. CURRAN: Well, Your Honor, on --

JUDGE CHAPPELL: Hold on, how about if I rule? The door was opened by complaint counsel. I'll allow it. If he doesn't know about it, that's fine, but the door was opened with reference to the 180-day period.

BY MR. CURRAN:

Q. So, Mr. Rosenthal, in 1998, Andrx filed an ANDA for a generic alternative to Prilosec, correct?

A. I believe so. I'm not sure of the exact date, but --

Q. Very good.

A. -- around then.

Q. The brand name company in question was AstraZeneca, correct?

A. That's correct.

Q. And AstraZeneca sued Andrx, correct?

A. Yes, they did.

Q. For patent infringement, right?

A. Correct.

Q. Within the 45-day period, right?

A. Correct.

Q. So that triggered a 30-month stay in which the FDA could not approve Andrx's ANDA, correct?

A. Could not grant final approval, correct; could have granted a tentative approval.

Q. Very good. Sir, that 30-month stay has expired, correct?

A. That is correct.

Q. But Andrx is still not on the market with its generic alternative to Prilosec, correct?

A. That's correct.

Q. Sir, Prilosec is the largest selling drug in the country, correct?

A. It's either that or Lipitor, it's one of the top two, yeah.

Q. Sir, Prilosec, in fact, is the largest selling drug in the world, isn't it?

A. Yes.

Q. If Andrx could introduce a generic alternative to Prilosec, Andrx would make a handsome sum of money, correct?

A. Yes.

Q. But Andrx is not on the market with its generic alternative to Prilosec, correct?

A. That's correct.

Q. But Andrx would very much like to be on the

market, correct?

A. That's correct.

Q. The annual sales of Prilosec are what, sir?

A. Approximately $4 billion in the U.S.

Q. $4 billion in the U.S. and about $7 billion worldwide, correct?

A. Correct.

Q. If Andrx could market a generic alternative to Prilosec, that would potentially be Andrx's biggest product, correct?

A. Without doubt.

Q. Without a doubt?

A. (Witness nods head.)

Q. And sir, today, as of right now, Andrx has final approval from the FDA, correct?

A. Yes, we do.

Q. And to repeat, the 30-month stay expired, and then the FDA granted final approval, right?

A. That's right.

Q. But Andrx is still not on the market.

A. That's right.

Q. And that's because it's too risky to go on the market while you're still in patent litigation with AstraZeneca, correct?

A. It's too risky at this stage of the patent

litigation, yes.

Q. Sir, if Andrx were to go to market and then lose the patent infringement suit, it would be -- it could be subjected to substantial damages, correct?

A. Yes.

Q. Under certain circumstances, there could even be treble damages, correct?

A. Yes.

Q. Sir, Andrx was also sued years ago by Hoechst for patent infringement in connection with Cardizem CD, correct?

A. Yes.

Q. And in that matter, Andrx likewise determined that it could not go to market with this generic product until it resolved the patent claims, correct?

A. Yes.

Q. Now, sir, this predicament about being kept off the market by pending patent litigation, that doesn't happen just to Andrx, correct?

A. Correct.

Q. In fact, there are numerous other generic companies with final FDA approval that have stayed off the market when there's pending patent litigation, correct?

MS. BOKAT: Objection, I don't believe counsel

has laid a foundation that Mr. Rosenthal knows about why other companies may not have gone to market.

JUDGE CHAPPELL: That's sustained. He's a fact witness, and he doesn't come in here with any presumed knowledge. You are going to have to lay a foundation before I allow that.

BY MR. CURRAN:

Q. Sir, at Teva, when you worked there for 13 years, there were occasions when Teva did not go to market even though it had FDA approval because there was a pend -- there was pending patent litigation, correct?

A. I'm not sure if there were any instances like that at Teva.

Q. I'll tell you what, let's put aside the reason for a moment why people stay off the market even if they have final FDA approval. The fact of the matter is, you are aware of numerous situations in which companies have not gone to market with their generic alternative even though they have FDA approval, correct?

MS. BOKAT: Objection. I don't believe there was any foundation laid for that question either.

MR. CURRAN: That -- Your Honor, I think that question sets its own foundation. I'm asking if he has

knowledge of that situation.

JUDGE CHAPPELL: Again, I'm at a disadvantage. I can't read the transcript. Would you read that back, Susanne, please?

(The record was read as follows:)

"QUESTION: I'll tell you what, let's put aside the reason for a moment why people stay off the market even if they have final FDA approval. The fact of the matter is, you are aware of numerous situations in which companies have not gone to market with their generic alternative even though they have FDA approval, correct?"

JUDGE CHAPPELL: I'll overrule the objection. That's a yes or no.

THE WITNESS: Yes.

JUDGE CHAPPELL: Mr. Curran, let's just take a break off the record, get your notes together, let's see if we can get my computer working.

MR. CURRAN: Very good, Your Honor.

(Pause in the proceedings.)

JUDGE CHAPPELL: Back on the record.

Proceed, Mr. Curran.

MR. CURRAN: Thank you, Your Honor.

BY MR. CURRAN:

Q. Mr. Rosenthal, we were discussing Prilosec, I

believe, when we stopped a moment ago.

Sir, the litigation brought by AstraZeneca against Andrx regarding the Prilosec generic, that's continuing today, correct?

A. As we speak.

Q. Quite literally, right?

A. Quite literally.

Q. There's a trial going on in the Southern District of New York, correct?

A. They're off today, but yes, it's ongoing.

Q. You get regular updates from there?

A. About five a day, yeah.

Q. Five a day. And that litigation began in 1998, correct?

A. I'm not sure of the start date.

Q. Does that sound about right, April 1998?

A. Probably in that area.

Q. That's over three and a half years ago, correct?

A. That we filed the Paragraph IV certification? Yeah.

Q. Yes, that you filed the Paragraph IV certification and then shortly thereafter were sued, right, sir?

A. Yes.

Q. Sir, every day that Andrx is off of the market from -- with its Prilosec generic, that's money out the window, correct?

A. Can you rephrase that question? I mean, there's a lot of ways to look at that. Money out the window by if I did it, I'd be throwing it out the window? Money if I didn't do it, I'm throwing money out the window? I mean --

Q. Fair enough. You'd like to have the Prilosec generic on the market today, right?

A. Yes, we would.

Q. Because you'd be making money doing that, right?

A. Yes, we would.

Q. And you'd be helping consumers, too, right?

A. Yes, we would.

Q. And every day that you're kept off the market by this patent litigation hurts Andrx, correct?

A. Yes, it does.

Q. And it hurts consumers, correct?

A. Yes, it does.

Q. And sir, sitting here right now, you don't know when, if ever, Prilosec will go on the market, do you, your Prilosec generic?

A. No, I don't.

Q. You've got no date certain as to when you can enter, correct?

A. Well, I can enter now, but at my -- at my risk.

Q. Okay, let me restate that. You have no date certain as to when you will enter, correct?

A. Correct.

Q. And sir, that litigation consumes considerable management time, doesn't it?

A. Yes, it does.

Q. You said a moment ago you get five updates a day?

A. Yes.

Q. You're not the only manager at Andrx who gets regular updates on that case, are you?

A. No, I'm not.

Q. Sir, AstraZeneca's the adversary in that litigation, right?

A. Yes.

Q. They're one of the biggest brand name pharmaceutical companies in the world, correct?

A. Yes.

Q. It's a deep pocket litigation adversary?

A. Yes.

Q. Formidable litigation adversary?

A. I'm not an expert in litigation adversaries,

so...

Q. Well, AstraZeneca's committing substantial resources to this litigation, correct?

A. I would assume so, yes.

Q. They've got a top flight New York patent infringement law firm, don't they?

A. I'm not competent to judge on the competency of their attorneys.

Q. But you're not going to market because there's a chance you could lose the lawsuit, right?

A. Right.

Q. And sir, are you familiar with the -- with AstraZeneca's Nexium product?

A. Yes, I am.

Q. Sir, while the litigation is pending on Prilosec, AstraZeneca is trying to develop a rival brand, correct?

A. Correct.

Q. And AstraZeneca is trying to shift consumers from Prilosec to Nexium, correct?

A. That's correct.

Q. That shift of consumers shrinks the market for Prilosec, correct?

A. Yes.

Q. That's another way that further delay in entry

of your Prilosec generic hurts Andrx, correct?

A. Correct.

Q. Because that Nexium product effectively competes with Prilosec, correct?

A. Yes, it competes in the same category.

Q. And sir, this trial that's going on right now in the Southern District of New York, that's the first trial on that case, correct?

A. Correct.

Q. Do you think there's going to be an appeal?

MS. BOKAT: Objection, Your Honor. I don't believe Mr. Rosenthal is a lawyer. I don't know that he has the foundation to answer that question.

MR. CURRAN: Your Honor, lawyers take their instructions from clients. Mr. Rosenthal's a client.

JUDGE CHAPPELL: Well, I'm giving you a little latitude on cross, because according to my notes, this witness talked about market entry, generic entry, new ANDAs, 180-day exclusivity period, effects on sales. So, I'm allowing some latitude to test those issues on cross exam.

If you want to ask him directly if he plans to appeal, whether it's his decision or not, I -- the objection is sustained to the extent you need to narrow the question a little bit.

MR. CURRAN: Very good, Your Honor.

BY MR. CURRAN:

Q. Mr. Rosenthal, if Andrx were somehow to lose this patent infringement suit, it would definitely appeal, correct?

A. That -- I'm not -- I don't -- that's not my decision. It depends how badly we would lose the case, I guess. There would be a lot of factors involved. It's a possibility. It's among the possibilities.

Q. Sir, it's a very strong possibility that Andrx would appeal, correct?

A. Again, it's -- I guess it's a function of how badly you lose the case, how bad the judge -- how strong the judge's decision is in favor of defending their patent -- of upholding their patent. I'm not saying we wouldn't appeal, but I'm not -- I don't know either way.

Q. Sir, this is a Bench trial, correct?

A. You mean --

Q. Do you know what that term means?

A. Meaning it's being heard by a judge alone?

Q. Yes.

A. Yes.

Q. No jury involved, correct?

A. That's correct.

Q. And the trial has been going on since December, correct?

A. The trial started in December, I believe, yes.

Q. And it's going to continue for at least several more weeks, correct?

A. That's our expectation.

Q. Sir, I'd like to talk a little bit about the ANDA that Andrx filed regarding K-Dur 10 and K-Dur 20. Sir, when you and I last spoke at your deposition in November, you knew that Andrx had filed an ANDA to develop an alternative to K-Dur 10 and 20, correct?

A. Correct.

Q. But you didn't know how long it had been pending, correct?

A. Correct.

Q. And you didn't know when Andrx began work on developing a generic to K-Dur 10 and K-Dur 20, correct?

A. How long prior to the submission of the ANDA, is that the question?

Q. Yes.

A. No, I didn't know.

Q. And sir, as of at least that time, November 2001, you were not kept informed on a regular basis of the status of Andrx's ANDAs, correct?

A. Of all of their ANDAs or the K-Dur ANDA?

Q. Well, let's start with the K-Dur ANDA.
A. I had less information on the K-Dur ANDA than I did on some of the other ANDAs.
Q. And sir, you were not kept informed on a regular basis of the status of that K-Dur ANDA, correct?
A. That's correct.
Q. Now, sir, at that time, you knew that the FDA had not granted even tentative approval on that ANDA, correct?
A. Correct.
Q. And sir, as we sit here today, the FDA still hasn't granted even tentative approval to that ANDA, correct?
A. Correct.
Q. Sir, when we spoke in November, you did not know what the outstanding issues were with the FDA, correct?
A. Correct.
Q. But you had reason to believe that Andrx was handling its K-Dur ANDA in a priority manner, correct?
A. That the -- that the handling of the ANDA fit into some kind of priority, is that your question?
Q. No. My question is, at that time, when we spoke in November, you had reason to believe that Andrx

was handling its K-Dur ANDA in a priority manner.

A. Well, to me "priority" denotes, you know, activity relative to something else. So, I'm still not clear as to your question.

Q. All right, let me add, in a priority manner in accord with Andrx's other priorities.

A. Yes.

Q. Sir, as a general matter, Andrx filed -- when Andrx files an ANDA, it wants to get approval, correct?

A. Correct.

Q. And it works toward that end, correct?

A. Yes, it does.

Q. And the K-Dur ANDA's no different, right?

A. Correct.

Q. Sir, are you aware that in October of 1999, Elliot Hahn of Andrx stated in an Andrx press release that the K-Dur ANDA was proceeding apace?

A. I'm not aware that he said that at that date.

Q. Would it surprise you to learn that he said that?

A. No, it wouldn't, not one way or the other. Elliot's our spokesperson, says a lot of things, makes a lot of public disclosures. So, he could have said that.

Q. Sir, Andrx is a publicly traded company, right?

A. Yes, we are.

Q. When it makes a -- when it issues a press release, it's pretty careful about what it says in that press release, correct?

A. Yes.

Q. It tries to make accurate statements, correct?

A. Yes.

Q. To the market and to its shareholders, correct?

A. Yes.

Q. Sir, if you could look at your screen for a moment, you'll see that this is an October 1999 -- October 6, 1999 press release from Fort Lauderdale, Florida -- that's where Andrx is headquartered, correct?

A. Yes.

Q. And the byline states, "October 6, 1999 -- Andrx Corporation," and I want to refer your attention to the second paragraph. Can you read that, sir? Can you read the underlined in red where it says, "We stay on top of these applications on a daily basis, and to the best of our knowledge, FDA review of Andrx's ANDA filings for generic versions of Prilosec as well as Naprelan, Tiazac, K-Dur, Wellbutrin and Zyban are all proceeding apace"?

A. I can see that.

Q. Sir, you don't dispute the accuracy of that statement, do you?

A. No.

Q. Sir, who is Diane Servello?

A. She's our -- I'm not sure of her exact title. She's the director or manager of regulatory affairs.

Q. And in that capacity, she's responsible for prosecuting ANDAs, correct?

A. She's responsible for the correspondence involved with ANDAs with the FDA.

Q. She shepherds the ANDA through the FDA regulatory process?

A. Right.

Q. Sir, to the best of your knowledge, as recently as November 2001, she did not know the terms of the Upsher-Smith/Schering-Plough patent litigation settlement agreement, correct?

A. I have no idea what she knew. I have to -- I'm supposed to know what Diane Servello knows? Is that what you're asking me?

Q. Well, my question was, she has -- as far as you know, she had no knowledge of the terms of the Upsher-Smith/Schering-Plough patent litigation settlement agreement.

MS. BOKAT: Objection, Your Honor.

THE WITNESS: I have no idea if she did or didn't.

JUDGE CHAPPELL: Mr. Rosenthal?

THE WITNESS: I'm sorry.

JUDGE CHAPPELL: You need to refrain from speaking when an attorney objects.

Were you finished? Mr. Rosenthal, were you finished?

THE WITNESS: Yes.

JUDGE CHAPPELL: What was your objection?

MS. BOKAT: My objection was going to be lack of foundation, because the witness had already indicated he didn't know what was in Ms. Servello's mind.

MR. CURRAN: Your Honor, I'll withdraw my question.

JUDGE CHAPPELL: I'll sustain it, because his answer indicates you were correct.

BY MR. CURRAN:

Q. But I would like to confirm that answer.

So, Mr. Rosenthal, it's your testimony that you don't know what Ms. Diane Servello knows about the Upsher-Smith/Schering-Plough patent litigation settlement agreement, correct?

A. Correct.

JUDGE CHAPPELL: Okay, I think we've confirmed that, so you can move on.

MR. CURRAN: Pardon me, Your Honor?

JUDGE CHAPPELL: I think we've confirmed that point.

MR. CURRAN: Well, my point, Your Honor, went beyond foundation.

Your Honor, at this time I would like to show this witness a series of documents between Andrx and the Food and Drug Administration with regard to Andrx's K-Dur ANDA. Most of those documents have been accorded in camera treatment. So, if that request of Andrx still stands, that these documents be accorded in camera treatment, I would ask that the room be cleared.

If, however, Andrx has reconsidered that position or Your Honor has concluded that there's been a waiver of some kind in the direct examination, then the room need not be cleared.

JUDGE CHAPPELL: I've ruled on outstanding motions for in camera treatment, so hasn't this been resolved, Mr. Shaftel?

MR. SHAFTEL: This is the first -- this moment is the first I have heard of any intention on the part of any of the parties to this proceeding of utilizing Andrx's documents designated confidential as part of

this proceeding. It is at least my understanding that notice ought to have been provided.

I do not know what documents counsel is referring to. Even today, I was not -- I have not been furnished a copy of what exhibits -- what intended exhibits they have in mind.

JUDGE CHAPPELL: Didn't Mr. Solomon of your firm file a motion for in camera treatment a few weeks ago? You're not aware of that?

MR. SHAFTEL: Judge, I am not aware of that, but again, I do not know what documents are being proposed.

JUDGE CHAPPELL: Well, I can assure you, Mr. Shaftel, there are some Andrx documents that have been granted in camera treatment. I've ruled on that, and I don't know if I have a list in front of me, but there are a number of documents -- perhaps Ms. Bokat or Mr. Curran have that list. They have exhibit numbers.

MR. CURRAN: Your Honor, I can confirm, I do not intend to show this witness any documents other than those that were previously identified to Andrx as to be disclosed in this proceeding, and Your Honor, yes, you did rule on Andrx's motion and granted in camera treatment to those documents.

JUDGE CHAPPELL: Okay, good. So, we've

established that they already are determined to be in camera.

MR. CURRAN: As of right now, they are.

JUDGE CHAPPELL: So, with that, then we will close the courtroom again to the public. So, if you are not subject to the protective order under this case, you will need to leave the courtroom, and I will have someone notify you when we open for public session again.

(The in camera testimony continued in Volume 8, Part 2, Pages 1700 through 1729, then resumed as follows.)

REDIRECT EXAMINATION

BY MS. BOKAT:

Q. Mr. Rosenthal, is it your personal belief that Upsher-Smith has the 180-day exclusivity period on their generic of K-Dur 20?

A. Yes, it is.

Q. Have you heard anything to the contrary at Andrx Pharmaceuticals?

A. No, I have not.

Q. Where Andrx believes that its competitor's drug has exclusivity, does that affect the priority of how Andrx works on its drug?

A. Yes, it does.

Q. What effect does it have?

A. Andrx would tend to prioritize those drugs that have the best return, that have the least impediments to making it to market, such as exclusivity or patent litigation.

MS. BOKAT: That's all I have on redirect, Your Honor.

MR. CURRAN: No recross for Upsher-Smith, Your Honor.

MR. LOUGHLIN: Nothing from Schering, Your Honor.

JUDGE CHAPPELL: Okay, with that, Mr. Rosenthal, you're excused. Thank you for your time, sir.

THE WITNESS: Thank you.

MS. BOKAT: Excuse me, Your Honor, before we conclude with this witness, does Mr. Shaftel want to say anything?

MR. SHAFTEL: I would, Your Honor. I know the day has been long. I have two just very brief housekeeping matters.

Of course, Your Honor disclosed excerpts from Mr. Rosenthal's deposition transcript in the other matter and provided in camera treatment in terms of its usage in this room. It was not used in the room today.

Respondents -- at least respondents' counsel do have hard copies, and I just want to clarify the treatment of those pages outside of the -- outside of the room. And in fact, since it was not made part of the record, I believe that probably can be returned with no prejudice to the parties.

JUDGE CHAPPELL: Do the respondents need to retain their copies?

MR. CURRAN: Your Honor, we would commit to treating them as all other in camera documents should Your Honor ultimately conclude that they should have in camera treatment. I just -- I hesitate to agree now to relinquish something without knowing if Mr. Rosenthal might come back as a rebuttal witness or whether there's some other reason for the document.

MR. LOUGHLIN: We have the same concern, Your Honor.

JUDGE CHAPPELL: All right, as long as they're not being used in the hearing or trial, they're not part of the public record, they are, in effect, merely produced documents that you would have gotten in discovery at this point. They are treated as I guess confidential or sensitive, whatever terminology you have in the protective order. They are, of course, not public.

What I'm trying to determine is whether Mr. Shaftel needs to file a motion for in camera treatment on these documents.

MR. SHAFTEL: To the extent --

JUDGE CHAPPELL: Why don't we go back to our rule that's in the pretrial scheduling order, I believe, an additional provision. If anyone intends to use any of those documents, any of that information, then you need to notify Andrx counsel so that he can file a motion to compel.

Is that acceptable to everyone?

MS. BOKAT: Just one point of clarification, Your Honor. I believe under the protective order, there were two categories of protection, confidential and then restricted attorneys' eyes only. I don't know whether Andrx has any preference as to category.

MR. SHAFTEL: If I could on the record --

JUDGE CHAPPELL: I'm sure he has a preference.

MR. SHAFTEL: -- today designate that material restricted confidential, the heightened designation.

JUDGE CHAPPELL: I'll let the attorneys work that out, because they're just discovery documents now, and if -- and you may need to stamp them or something. You know, you just need to handle that. That's housekeeping for you.

For my purposes, I've previously granted provisional in camera status to those documents, and based on what I'm hearing, I can withdraw that provisional in camera treatment of those documents, and I'll do so on the record. In the event someone's going to use those documents and they're going to be placed or attempted to be placed in the public record, then, Mr. Shaftel, you'll need to file a motion for in camera treatment. Is that clear?

MR. SHAFTEL: Yes, Your Honor.

JUDGE CHAPPELL: Any more questions on this matter?

MR. SHAFTEL: Just one or two more.

My colleagues mentioned calling Mr. Rosenthal back. In fact, I believe it was Schering also served a subpoena on Mr. Rosenthal today. Your Honor did not limit any of the questions based on scope, going beyond the scope of the direct. Mr. Rosenthal has been here to address all questions, and I see no need for him to come back, and I would ask that his appearance today be deemed satisfaction of the subpoena that Schering served on him.

JUDGE CHAPPELL: Do you agree to that?

MS. SHORES: Well, first of all, it's news to me that we served a subpoena on Mr. Rosenthal today.

MR. SHAFTEL: I'm sorry, I did not mean to characterize the service being effectuated today.

MS. SHORES: Okay, I think we did that in the normal course, because he is on our witness list as well as everybody else's witness list. We have no current intention of calling Mr. Rosenthal back.

MR. SHAFTEL: Thank you.

MR. CURRAN: Nor does Upsher-Smith, Your Honor. When I said rebuttal, I meant complaint counsel's rebuttal case. I have got --

JUDGE CHAPPELL: So, are you releasing him from the subpoena?

MR. CURRAN: I don't believe I served a subpoena on him, so --

MR. SHAFTEL: Schering, Schering did.

MS. SHORES: Oh, he's free to go.

JUDGE CHAPPELL: Okay, Mr. Shaftel, anything else?

MR. SHAFTEL: Thank you, Judge.

JUDGE CHAPPELL: Good day for you, I believe. With that, you are excused.

THE WITNESS: Thank you.

JUDGE CHAPPELL: Ms. Bokat?

MS. BOKAT: Yes, Your Honor?

JUDGE CHAPPELL: What's next for complaint

counsel?

MS. BOKAT: Could I take up a couple of housekeeping matters before we go into our readings? Would that be acceptable?

JUDGE CHAPPELL: Yes, you may.

MS. BOKAT: This morning when I was asking Mr. Rosenthal about CX 52, Mr. Curran and I thought that maybe it was going to be -- supposed to be a multipage document. We conferred at the break, and now our belief is that it's proper as CX 52, a single-page document.

MR. CURRAN: That's correct, Your Honor. I was mistaken when I said it was multipage. I was looking at USX 52. CX 52 is a single page.

MS. BOKAT: And it's already been admitted, so I'd like to have it just stand as is. I had said to Your Honor this morning, thinking it was supposed to be a multipage, that we would be submitting more pages. Now that appears not to be necessary, so I would like to just stand with the single page for CX 52.

JUDGE CHAPPELL: Okay, and it has been admitted already?

MS. BOKAT: You admitted it, yes.

JUDGE CHAPPELL: All right. Anything else?

MS. BOKAT: Yes, if I haven't tried the Court's

patience yet. Yesterday we were talking about JX-3, which was a list of -- it's a joint stipulation.

JUDGE CHAPPELL: Yes, I have a copy.

MS. BOKAT: You have it, okay, listing SPXs, those are Schering exhibits, and CXs, complaint counsel's exhibits. The Court admitted JX-3 yesterday, but it occurred to me at 5:45 a.m. this morning that I had perhaps overlooked a formality. I went back and checked the transcript, and indeed yesterday I did not formally offer the CXs listed in that JX-3. So, I thought perhaps I should read those numbers and formally offer them in evidence just so we would have a clear record?

JUDGE CHAPPELL: I think if they are clearly typed into JX-3, I admitted the documents. I admitted the exhibits that are part of JX-3. So, you don't need to read them on the record.

MS. BOKAT: Thank you, Your Honor.

JUDGE CHAPPELL: Next?

MS. BOKAT: Then I think we're prepared to proceed with readings.

JUDGE CHAPPELL: Yes. I just want to make one thing clear on the record. I wasn't reading the transcript. I just want to make it clear, I vacated my previous ruling granting in camera status to the

testimony or the deposition testimony of Mr. Rosenthal.

You may proceed.

MS. BOKAT: Thank you, Your Honor. I call on Ms. Apori and Mr. Ginsburg to resume the readings where we left off yesterday afternoon.

Your Honor, we would like to resume with readings from Mr. Wasserstein. At the conclusion of the day yesterday, we had had readings from Mr. Wasserstein's investigational hearing. We would like to pick up with readings from his deposition that was conducted October 10th, 2001.

JUDGE CHAPPELL: Please proceed, Mr. Ginsburg.

MR. GINSBURG: Thank you, Your Honor.

Page 7, line 17:

"MR. EISENSTAT: I'd like to have marked as Wasserstein Exhibit 1 a 12-page document bearing the numbers SP 018744 through SP 018755.

"QUESTION: Mr. Wasserstein, you've been handed what's been marked as Exhibit 1. I'd ask you to look that document over and tell me if you recognize the document.

"ANSWER: Yes, I do.

"QUESTION: And what is the document?

"ANSWER: It is a financial and capital

planning section, subject matter acquisition/divestiture, joint venture and licensing proposals, Schering-Plough corporate policy from the finance manual.

"QUESTION: What's the finance manual?

"ANSWER: It is a set of policies and procedures for Schering-Plough that's given to all of the financial contacts within the company.

"QUESTION: In the lower left corner of the first page, there's a block called Sponsor. Do you see that?

"ANSWER: Yes.

"QUESTION: And it says J. A. Wasserstein in that block.

"ANSWER: Yes.

"QUESTION: Is that you?

"ANSWER: Yes.

"QUESTION: What does it mean to be a sponsor?

"ANSWER: It means to be the person who wrote the policy and put it forward."

MR. GINSBURG: Page 11, line 10:

"QUESTION: Could you turn to the second page of the document, the page bearing

document identification number SP 018745, and do you see around the middle of the page a heading called Policy?

"ANSWER: Yes.

"QUESTION: And the first sentence under there says, 'The sponsoring unit has final responsibility for the preparation and submission of the proposal for any transaction.' Do you see that sentence?

"ANSWER: Yes.

"QUESTION: My question to you is, who was the sponsoring unit for the license by which Schering licensed Niacor-SR from Upsher-Smith?

"ANSWER: We have or had at the time sort of a loose, very decentralized system. So for this transaction, it was probably a combination of Mr. Kapur's unit, which was Warrick Pharmaceuticals, Global Marketing and the, indirectly, the European business operations."

MR. GINSBURG: Page 49, line 16:

"QUESTION: Did you do any due diligence for this licensing agreement?

"MS. SHORES: Objection, vague. What do you mean by due diligence? If you understand

what he means by 'due diligence' you can answer it. Otherwise, I don't know how you can answer.

"ANSWER: Based on that, could you just be a little bit more specific in terms of what you mean by due diligence?

"QUESTION: When you talk about licensing products at Schering, do you ever talk about doing due diligence on the license?

"ANSWER: Due diligence is a term for -- I guess that people generally use for some form of research. In this case, because I was brought in later in the transaction and basically to help Mr. Kapur with the final negotiations on the transaction that others had been working on for a while, I did not do any independent research or analysis on my own and relied on what the others who were involved in the transaction were telling me."

MR. GINSBURG: Page 51, line 15:

"QUESTION: When you license products from other companies at Schering, in your experience, do people generally go and visit the other company and review their information before that license is signed?

"MS. SHORES: Objection, vague.

"ANSWER: It depends on the transaction. And, again, that's always been somebody -- when I was doing these transactions, somebody else's responsibility to go do that.

"QUESTION: So, you never had responsibility for doing that --

"ANSWER: No.

"QUESTION: -- in the licenses you worked on?

"ANSWER: That's correct.

"QUESTION: And you didn't have that responsibility in the Upsher/Schering license agreement?

"ANSWER: Did not, no.

"QUESTION: Do you know if someone did?

"ANSWER: I don't know.

"QUESTION: Do you know if anybody actually went to Upsher-Smith and reviewed any files of information on FDA correspondence?

"ANSWER: I don't.

"QUESTION: Do you know if anybody went to Upsher-Smith and reviewed any files on intellectual property rights?

"ANSWER: I don't."

MR. GINSBURG: Page 96, line 11:

"QUESTION: Do you know if the Schering controller ever reviewed the license for Niacor-SR before it was signed?

"ANSWER: I don't know.

"QUESTION: Do you know if the Schering tax department reviewed the license for Niacor-SR --

"ANSWER: I don't recall.

"QUESTION: -- before it was signed?

"ANSWER: I don't recall.

"QUESTION: Do you know if the Schering treasury department reviewed the license for Niacor-SR before it was signed?

"ANSWER: I don't recall."

MR. GINSBURG: That's all, Your Honor, we have from Mr. Wasserstein's deposition. Thank you.

MS. SHORES: Your Honor, we do have some counter-designations, and Mr. Jason Raofield and Mr. Koons will be handling those on behalf of Schering.

JUDGE CHAPPELL: Thank you. You may proceed.

MR. RAOFIELD: Page 7, line 17, complaint counsel questioning the witness:

"MR. EISENSTAT: I'd like to have marked as Wasserstein Exhibit 1 a 12-page document

bearing the Bates numbers SP 018744 through SP 018755.

"QUESTION: Mr. Wasserstein, you've been handed what's been marked as Exhibit 1. I'd ask you to look that document over and tell me if you recognize the document.

"ANSWER: Yes, I do.

"QUESTION: And what is the document?

"ANSWER: It is a financial and capital planning section, subject matter acquisition/divestiture, joint venture and licensing proposals, Schering-Plough corporate policy from the finance manual."

MR. RAOFIELD: Page 12, line 6, complaint counsel questioning the witness:

"QUESTION: The next paragraph in that section starts, "During the investigation of a potential transaction, the sponsoring unit will contact the staff vice president-business development to inform him and request corporate guidance or assistance as appropriate." Do you see that sentence?

"ANSWER: Yes.

"QUESTION: Were you the staff vice president-business development?

"ANSWER: Yes.

"QUESTION: When it says the sponsoring unit will contact the staff vice president, who in this kind of arrangement was supposed to contact you?

"ANSWER: In this case, the primary contact that I had was Jim Audibert in Global Marketing, but I also had contact with Mr. Kapur."

MR. RAOFIELD: Page 35, line 7, complaint counsel questioning the witness:

"QUESTION: Do you recall if Mr. Audibert told you anything about -- in these phone conversations you had with him before the meeting whether Mr. Audibert told you anything about what he learned when he was working on the Kos project?

"ANSWER: In my conversations with Jim I recall he made it clear that he was aware of the value of sustained niacin products and in general the value of the market because of some work that he had done or some information that he had about Kos, yes."

MR. RAOFIELD: Page 50, line 22, complaint counsel questioning the witness:

"QUESTION: Do you recall any license you ever worked on at Schering where you were licensing a product that was not yet approved where someone didn't go through the company's, the company whose product you were licensing, files of correspondence with the FDA?

"ANSWER: In all the times that I worked on transactions, I only recall one time when I personally went through an FDA correspondence file. So I'm not aware of the other -- in the other transactions what was or wasn't done."

MR. RAOFIELD: Page 98, line 14, complaint counsel questioning the witness:

"QUESTION: And you have no recollection, no specific recollection of the person in that job actually contacting the controller, the tax department or the treasury department?

"ANSWER: I don't have any specific recollection, no.

"QUESTION: Was that supposed to have been done?

"ANSWER: For a transaction like this where there was no particular issue, since it was a straight up-front prepaid royalty and there was no other bell or whistle, there was

nothing unusual about it. So, if they weren't talked to specifically for input, that wouldn't have been a big surprise."

MR. RAOFIELD: That concludes Schering's counter-designations, Your Honor.

JUDGE CHAPPELL: Thank you.

Anything from Upsher?

MR. CARNEY: None from Upsher, Your Honor.

MS. BOKAT: Complaint counsel will continue with the investigational hearing transcript of Thomas Lauda. This investigational hearing was conducted September 12th, 2000. Mr. Lauda was a Schering employee, head of global marketing, I believe.

MS. SHORES: That's correct, Your Honor.

JUDGE CHAPPELL: You may proceed.

MR. GINSBURG: Thank you.

Page 86, line 2:

"QUESTION: Do you recall when you first heard that Schering-Plough was considering taking a license to market the Niacor-SR product?

"ANSWER: I don't recall an exact date. I do recall a conversation from Ray Kapur who informed me that they had an opportunity to license several projects -- several products,

from Upsher, that the principal one was a European or international opportunity for Niacor and could I perform an assessment of that against a background that the value would probably -- the payment would probably be about $60 million.

"QUESTION: So, Mr. Kapur told you the payment would be around $60 million?

"ANSWER: He told me that was the expected range, yes.

"QUESTION: Would this have been in 1997?

"ANSWER: It would have had to have been, yeah, because we did the assessment sometime in that -- it would have had to have been around there.

"QUESTION: And Mr. Kapur was the one who told you this?

"ANSWER: Yes."

MR. GINSBURG: Page 87, line 13:

"QUESTION: Did he tell you anything about the $60 million in payments?

"ANSWER: It was unclear to me at the time. He did tell me that there were I think three or four products involved. I was unclear of what the other products were. I knew they

were for the U.S. market, but this was an opportunity for the international market and his feeling, I think my recollection is, he felt that the European opportunity had to carry the ball on the bulk of the 60 million.

"QUESTION: Could you --

"ANSWER: My understanding was the European opportunity would have to carry the -- be able to carry, justify the payments.

"QUESTION: So that the --

"ANSWER: In other words, to get the opportunity, I would have to be able -- the opportunity would have to present a return to me on a $60 million up-front payment.

"So, the European sales and profitability would have to be sufficient to cover a $60 million up-front -- the opportunity would cost us $60 million, is what he basically told me. Even though I know there were three other or four other products, and I don't recall what they were, he had told me they were not -- these were not going to contribute.

"What he was trying to do is help me understand what would be the -- what I would -- what would be the value of the

opportunity I was looking at, how -- not the value -- what we would have to pay and what it would be worth.

"So what I was looking at was an opportunity for that product that would cost me $60 million, was that an opportunity that we would be interested in, and so that was the basis for our assessment.

"QUESTION: And it was your understanding that it was going to be Europe that was going to be the primary market?

"ANSWER: Well, Europe was the primary market because Europe represents about 85 percent of our international sales. Japan we almost generally always exclude because it takes so long to register almost anything in Japan, so we were looking primarily in Europe."

MR. GINSBURG: Page 102, line 2:

"QUESTION: Did you have any conversations that you recall now with Mr. Audibert when you first initiated this project?

"ANSWER: Nothing out of the ordinary other than, you know, we needed to get this done and that -- nothing that I can recall.

"QUESTION: Do you recall if you told him about the $60 million payment?

"ANSWER: I think I did.

"QUESTION: Do you recall if you told him that Europe would have to carry the load, so to speak, in justifying it?

"ANSWER: I may have, but he would have known that.

"QUESTION: That's something --

"ANSWER: It's just -- our business is 80 percent Europe, our international business.

"QUESTION: Do you recall any conversations with anybody else regarding this matter while Mr. Audibert was working on this analysis?

"ANSWER: I don't think I had conversations with -- other than Ray Kapur, which I've already mentioned."

MR. GINSBURG: Page 104, line 17:

"QUESTION: Is there a minimum financial return that a project has to return before you'd be interested?

"ANSWER: We do that. We have a -- when we do our NPVs or our net present value, we would probably have a discount rate, which that discount rate is to represent what we could

earn by leaving money in the bank.

"But again, these are all guidelines. There's no firm criteria either in my organization, with me or with my superiors that would say here's the ABCs of evaluating a project. We just don't do it. We look at each one independently.

"QUESTION: Could you explain for the record what NPV is?

"ANSWER: It's a net present value. What that means is what would my earning stream be after my investment in today's market.

"QUESTION: So, it gives you a single value for a future stream of earnings?

"ANSWER: Yes, it does. And by the way, that in itself is not a total criteria. It's an indicator.

"QUESTION: What do you mean by that?

"ANSWER: Well, you know, if I'm losing money the first five years, I may not want to do that deal anyway, because my risk is I'm only going to make money ten years from today. It may also be I have strategic reasons to do the deal, and so the financials are not the only criteria that I would go by.

"QUESTION: Okay. Let me see if I understand. Even if the net present value showed that it had a net present value greater than what it cost you, if you looked at the actual distribution of when you had to make payments and when you had cover returns, you might decide that you're not interested in the project?

"ANSWER: For a lot of reasons, not just that, there are many reasons.

"QUESTION: Is that one of the reasons you could decide that --

"ANSWER: It could be.

"QUESTION: -- it didn't fit within your business?

"ANSWER: Could be.

"QUESTION: So that's what you mean when you say net present value --

"ANSWER: Net present value is to give you a financial indication of your return in current dollars.

"QUESTION: But it's not the decision-making criteria?

"ANSWER: It's not the decision. There is no unified decision-making criteria in

Schering-Plough."

MR. GINSBURG: Page 131, line 4:

"QUESTION: And then the following page, which is the last page in the document, labeled SP 1600047, is labeled Table 2: Niacor-SR Sales in Million Dollars. Do you see that?

"ANSWER: Yes.

"QUESTION: Now, these aren't actual sales, these are just projections, right?

"ANSWER: These are projections, right."

MR. GINSBURG: Page 132, line 14:

"QUESTION: But all these estimates depend on the product getting FDA approval, don't they?

"ANSWER: With this -- well, getting European approval.

"QUESTION: Yes. I stand corrected because we're talking international.

"ANSWER: Right.

"QUESTION: All these require getting European approval; is that correct?

"ANSWER: That's correct.

"QUESTION: And if they don't get European approval, what would the sales be in each

year?

"ANSWER: It depends on what markets don't get approved.

"QUESTION: So, assume they get no approvals?

"ANSWER: The sales would be zero if they had no approvals, pretty much.

"QUESTION: So, if they don't get approvals, you'll have essentially no sales?

"ANSWER: That's correct.

"QUESTION: Did you make any estimate of the likelihood that they were going to get approvals in Europe?

"ANSWER: I don't think -- did we make any -- we assumed that it would.

"QUESTION: You just assumed it would?

"ANSWER: We assumed that it would."

MR. GINSBURG: Page 134, line 11:

"QUESTION: But in fact you were simply wrong there; right?

"ANSWER: Right. That's correct.

"QUESTION: And it was not approved by Europe?

"ANSWER: It wasn't submitted, so it wasn't a question of being approved. The reason this

product didn't move forward was because it had to be reformulated and retested.

"QUESTION: Because those clinical trials that hadn't been complete came out with disappointing results?

"ANSWER: That's correct.

"MR. EISENSTAT: I'd like to have marked as the next Lauda exhibit in order, Exhibit 5, a two-page document bearing the numbers for identification SP 1600035 through SP 1600036.

"QUESTION: You've been handed what's been marked as Lauda Exhibit 5 and I ask you to look at that document and see if you recognize what it is.

"ANSWER: Yeah. It's the P&L that accompanied our assessment.

"QUESTION: Is this something that Mr. Audibert sent?

"ANSWER: Yes. But something I would have reviewed as key to the project."

MR. GINSBURG: Page 137, line 8:

"QUESTION: Okay. And again, your assumption underlying this is that the Niacor-SR product would get the dossier approval in Europe?

"ANSWER: Absolutely. With the proper labeling.

"QUESTION: Yeah, with the label that permitted it to be sold as a cholesterol-treating product?

"ANSWER: That's correct."

MR. NIELDS: Your Honor, the word "product" was converted to "project" in one of the questions. In other words, Mr. Ginsburg said "project" and it should have been "product."

MR. GINSBURG: If that's true, I apologize. I meant to say "product."

JUDGE CHAPPELL: Could you find the page and line number?

THE REPORTER: I have already corrected it.

JUDGE CHAPPELL: Okay, thank you, Mr. Nields. Proceed.

MR. GINSBURG: Page 142, line 21:

"QUESTION: Do you know if the plan was first to get FDA approval in United States and then get -- try to get dossier approval in Europe or if it was independent?

"ANSWER: It would come the following way. They would assemble a dossier for their approval in the United States. That would be

their HRD, health registration. They would give us that. We would then convert that into an approvable form because their formats and requirements are different. We would have formatted that for the EU and filed it in the EU and the rest of the world.

"QUESTION: Okay. So, you could have -- would you essentially be filing it at the same time they were?

"ANSWER: We would probably file behind them, and the reason for that is they would -- you know, the nicer way to do it, they give us the file, we take that file, slice and dice it, change it around, put it into the -- and we would have to have an expert's report, which is a requirement that's outside of what the U.S. would require, so we'd have to take that -- all of the clinical work, take it to an outside expert in Europe and they would write a recommendation and then we would submit. But the format is quite different.

"QUESTION: Okay. So, there was no requirement that you have FDA approval, though, before you go --

"ANSWER: No, no."

MR. GINSBURG: Thank you, Your Honor, that's all we have for Mr. Lauda's investigational hearing.

JUDGE CHAPPELL: Anything from --

MR. RAOFIELD: Yes, Your Honor.

JUDGE CHAPPELL: And these are Schering's counter-designations?

MR. RAOFIELD: To Mr. Lauda's investigational hearing, yes, Your Honor.

Page 86, line 13:

"QUESTION: So Mr. Kapur told you the payment would be around $60 million?

"ANSWER: He told me that was the expected range, yes.

"QUESTION: Would this have been in 1997?

"ANSWER: It would have had to have been, yeah, because we did the assessment sometime in that -- it would have had to have been around there.

"QUESTION: And Mr. Kapur was the one who told you this?

"ANSWER: Yes.

"QUESTION: Did he -- let me back up a step. At the time did you know you were in litigation with Upsher-Smith over the potassium chloride patents?

"ANSWER: No.

"QUESTION: You did not?

"ANSWER: I did not know.

"QUESTION: Did Mr. Kapur tell you that?

"ANSWER: No.

"QUESTION: Did anyone tell you that?

"ANSWER: No."

MR. RAOFIELD: Excuse me, Your Honor, that should have read, "Did anybody tell you that?"

"ANSWER: No.

"QUESTION: Did Mr. Kapur tell you anything about the reason they had this opportunity to license the products?

"ANSWER: He just simply presented that that was the opportunity and could I do an assessment."

MR. RAOFIELD: Page 90, line 23:

"QUESTION: Do you recall if he gave you any information about the product?

"ANSWER: There was probably a very brief discussion. He had asked who in my group would handle that, and I had -- at that time Jim Audibert was on my staff and I had told him that Jim would be the person providing the assessment.

"He had indicated that he would send over the package that he had and that he had given me the parameters for what was -- for what the basis of the deal was, which were these four products, niacin, which was the main one, and that he had indicated that it would probably carry a price tag of $60 million, was it an opportunity that we wanted to pursue.

"Then I called Jim Audibert and asked Jim to head up the project since this was a cardiovascular area."

MR. RAOFIELD: Page 133. Your Honor, at this time, it appears to be approximately eight lines, three question and answers from complaint counsel's designation that I'm required to read in order to put in context our counter-designation.

JUDGE CHAPPELL: That's fine, thank you.

MR. RAOFIELD:

"QUESTION: So, if they don't get approvals, you'll have essentially no sales?

"ANSWER: That's correct.

"QUESTION: Did you make any estimate of the likelihood that they were going to get approvals in Europe?

"ANSWER: I don't think -- did we make

any -- we just assumed that it would.

"QUESTION: You assumed it would?

"ANSWER: We assumed that it would."

MR. RAOFIELD: At this point I will begin reading the counter designation, Your Honor, page 133, line 13, complaint counsel questioning the witness:

"QUESTION: Were you told to assume it would?

"ANSWER: No.

"QUESTION: Why --

"ANSWER: Because we would -- what we looked at based upon the product that we were dealing with, the characterization of the technology, we assumed that -- first of all, niacin is approved, okay?

"A sustained-release niacin is what we were looking for, was an approval with a specific label that had reduced side effects.

"So, the fact that would a niacin be approved? Almost certainly. Would a sustained-release -- not almost certainly. Certainly. It is approved. Would a sustained-release be approved? Very, very likely. Would a sustained-release be approved that had those characteristics? Based upon

what we saw, it was a highly likely event.

"QUESTION: When you say 'highly likely,' could you put a probability on that?

"ANSWER: You know, I don't -- I hate to stick a number, because I don't think I should, but highly likely.

"QUESTION: More likely than not?

"ANSWER: Oh, absolutely."

MR. RAOFIELD: That concludes Schering's counter-designations for this investigational hearing, Your Honor.

JUDGE CHAPPELL: Thank you.

Upsher?

MR. CARNEY: Upsher-Smith's designations are contained in what was read by Schering. We have nothing to add, Your Honor.

MS. BOKAT: The next readings come from the deposition transcript of Thomas Lauda. That deposition was taken September 24th, 2001.

JUDGE CHAPPELL: Thank you. You may proceed, Mr. Ginsburg.

MR. GINSBURG: Thank you. Page 37, line 19:

"MR. EISENSTAT: Before we get to that, let me have marked as Lauda Exhibit 4 Respondent Schering-Plough Corporation's Statement of the

Case Involving Schering and Upsher-Smith, and I apologies, I only have two copies of it with me.

"QUESTION: Mr. Lauda, let me hand you what's been marked as Lauda Exhibit 4, and this is Schering-Plough Corporation's statement of the case involving Schering and Upsher-Smith that was filed with the court in this matter, and let me ask you to turn to the second page and feel free to read any part of it you want. I'm not trying to hide anything from you, but let me direct your attention to the first two full paragraphs on page 2 and could you just, I guess the easiest thing is if you could just read into the record those first two full paragraphs.

"MR. NIELDS: Why don't you just read them into the record.

"QUESTION: After discovery had largely concluded and as the trial date was approaching, the parties engaged in settlement discussions. The parties discussed a settlement under which Schering would grant Upsher a license to market its product for part of the life of Schering's patent.

Schering had flatly rejected the idea that it should pay money to Upsher as part of the settlement. One week before trial no settlement had been reached. Upsher then offered to sell Schering the rights to market, outside the United States, Niacor-SR, a product which Upsher had in development. Niacor-SR was a sustained release niacin product for treatment of elevated cholesterol. This offer was of significant interest to Schering, which had recently tried, unsuccessfully, to acquire rights to a very similar sustained-release niacin product from another company.

"Two Schering officials, who were not made aware of the patent lawsuit, evaluated the proposed Niacor-SR license and concluded that it was worth more to Schering than the price Upsher was asking.

"Do you see those two paragraphs?

"ANSWER: Yes.

"QUESTION: Do you know who those two Schering officials were?

"ANSWER: No.

"QUESTION: Did you evaluate the proposed

Niacor-SR license?

"ANSWER: Yes.

"QUESTION: How did you evaluate the license if you never saw it?

"ANSWER: Well, Ray sent me a package that included all of the clinical work that Niacor -- or rather, that Upsher had provided us. Based upon that clinical package and the data that was in there we had a profile of the product. Ray had mentioned to me that, and I did not pass it on to Jim Audibert, but Ray had mentioned to me that it was an arrangement that they were looking to have a value of about $60 million, was it worth $60 million I think is the way Ray basically phrased the question, and asked me to do an assessment based upon the profile that we were provided.

"QUESTION: But how did you evaluate the license if you'd never seen the license?

"MR. NIELDS: I'm sorry, do you mean a written license agreement?

"ANSWER: I never saw the written license agreement.

"QUESTION: Did you ever evaluate a written license agreement?

"ANSWER: I evaluated a licensing opportunity.

"QUESTION: What is a licensing opportunity?

"ANSWER: Well, as I'm saying, that there was a profile of a product, that they were asking us to do -- asking us what do we think it was worth, and that's what we did. I presumed that there was a license to be wrapped around it.

"QUESTION: But you never saw any such license?

"ANSWER: I never saw it nor did I participate.

"MR. NIELDS: Wait a minute, you never saw a license agreement?

"QUESTION: You never saw a license.

"ANSWER: An agreement, a licensing agreement, I never saw that, no.

"QUESTION: You never evaluated the terms of any licensing agreement between Upsher and Schering?

"ANSWER: I would say no to that because I've never seen the terms. I evaluated a licensing opportunity."

MR. GINSBURG: Page 41, line 17:

"QUESTION: The second full paragraph on page five says, 'Mr. Audibert, who was unaware of the patent litigation, reviewed the information concerning Upsher's clinical trials and did a written financial assessment of the proposed Niacor-SR license. His work was reviewed by Thomas Lauda, who was the executive vice president in charge of Global Marketing, and who was also unaware of the patent lawsuit. Mr. Lauda concluded that the license rights to Niacor-SR were worth considerably more than Upsher was asking.' Did you conclude that the license rights to Niacor-SR were worth considerably more than Upsher was asking?

"ANSWER: That's correct. And my understanding at the time was that that was a $60 million licensing fee, and our financial evaluation showed that it could, in a conservative format, significantly exceed that.

"QUESTION: Do you know what licensing rights Schering was actually getting in the licensing agreement?

"ANSWER: No, no. I presumed -- I mean, we made a presumption that it was a licensing right to Niacor sustained-release. What the terms were I did not know other than Ray informed me that it would involve $60 million.

"QUESTION: If you didn't know what the terms were, how could you conclude that the license rights to Niacor-SR were worth considerably more than Upsher was asking?

"ANSWER: On one basis. Ray said that it would involve $60 million of value. However that was sent it was irrelevant to me because it was, even if it was cash, it was worth more than $60 million.

"QUESTION: I'm not asking what was sent; I'm asking what you were getting. Do you know what licensing rights Schering was getting?

"ANSWER: No.

"QUESTION: So how, if you didn't know what licensing rights Schering was getting, how could you conclude that those licensing rights were worth considerably more than Upsher was asking?

"ANSWER: Well, first, a package was sent to Ray with the full details but Ray had

informed me that it was a $60 million license right acquisition, if you want. Was it worth $60 million? That's a relatively simple question to answer. Yes. How if you're asking me were there other caveats in there, I presumed that it was a straightforward $60 million fee involved and it was worth that, the financial analysis showed us and the commercial analysis showed it was worth it. So again I think I stand by that and if you ask me to do it again, today I would come back and tell you if you were paying $60 million for the product with that potential, is it worth it, the answer would be yes.

"QUESTION: When you say you're paying $60 million for the product with that potential, what product were you talking about?

"ANSWER: Niacin sustained-release.

"QUESTION: Any niacin sustained-release product?

"ANSWER: We had a product profile and clinical profile which was rather detailed, so we knew the product that we were talking about. I mean, I think if you're asking me do I know what all the terms were, the answer is

no. I've never seen all the terms. I knew there were other products involved in the licensing. Ray told me there were other generic but this was the principal product and I think it would have to carry $60 million, was it worth it, and the answer was yes.

"QUESTION: Do you know if there were -- was any term in the license agreement between Upsher-Smith and Schering-Plough that would have prevented Upsher-Smith from simply pocketing the $60 million and walking away from the product?

"ANSWER: No.

"QUESTION: If there were no such term in the agreement, if under this agreement Upsher-Smith was completely free to pocket the $60 million, abandon the product and walk away, would this license agreement still have been worth $60 million?

"ANSWER: I think I would say that the project was worth $60 million. I'm not sure I understand your question. If they could just take -- if you're telling me Upsher would take $60 million, put it in its pocket and leave us with nothing, the answer is that's not worth

it, but the project itself and the state of -- let me finish the answer, okay -- the project itself and the state of its clinical development, when I consider that niacin is, in fact, a very well known entity, that sustained-release is a very well known technology, our assessment of that project was that it would end up being a product in the marketplace and my personal assumptions would be why would they do that? Now, what the terms were in the contract I can't answer to, I don't know how to address your -- you know, if you're saying should there have been provisions to prevent them from walking away, I don't know if there were or there weren't.

"QUESTION: I'm asking you to assume that there were no provisions to prevent them from walking away and would you still think the license is worth $60 million?

"ANSWER: But you're asking me, I think what you're asking me is if Upsher walked away with $60 million, is that worth it, I would tell -- the answer is no. If I had the opportunity to bring this market to product for $60 million, the answer is yes, because

even if I took it myself, I would start, I don't know what those provisions were what."

MR. GINSBURG: Page 49, line 3:

"QUESTION: Do you know if regulatory affairs was involved in the Upsher-Smith/Schering license agreement?

"ANSWER: Not that I know of. Jim had them as available to him if he needed them but I don't know that they were or they weren't.

"QUESTION: Do you know if anybody went back and checked the correspondence between the FDA and Upsher-Smith?

"ANSWER: Not that I know of."

MR. GINSBURG: Page 50, line 3:

"QUESTION: Do you know what a PK study is?

"ANSWER: Yes.

"QUESTION: What's a PK study?

"ANSWER: Well, it's a study designed to determine what the blood levels of a drug are.

"QUESTION: Is a successful PK study or an accepted PK study a requirement to get a new drug approval?

"ANSWER: Yes.

"QUESTION: If Upsher-Smith was unable to meet the FDA's requirements for PK study,

would that be something you would want to know before you spent $60 million on this product?

"ANSWER: I think we would want to know the status of a PK study.

"QUESTION: That's pretty basic stuff, isn't it?

"ANSWER: Well, I don't know if it's basic, but I think we would want to know. We would want to know the outcome of the clinical trial. As you go through, there is a pile of work done there that you'd like to know.

"QUESTION: Do you know if anybody checked on that for Schering?

"ANSWER: I don't know."

MR. GINSBURG: Page 53, line 8:

"QUESTION: Did David Poorvin work on the Upsher-Smith?

"ANSWER: No.

"QUESTION: Why not?

"ANSWER: He wasn't asked to, it's not unusual that -- we don't do all the business development deals in Schering-Plough. It's not unusual to have done it but it was outside of us.

"QUESTION: So, the Upsher-Smith/Schering

deal was essentially done by a group outside of yourself?

"ANSWER: Yes.

"QUESTION: And which group was that?

"ANSWER: I presume it was Ray Kapur and Jeff Wasserstein. Jeff at that time was a business development group."

MR. GINSBURG: Page 56, line 22:

"QUESTION: But as far as you know, looking at the Upsher-Smith/Schering agreement, nobody from your group looked at the regulatory materials for Upsher-Smith?

"ANSWER: No, that's not true. Jim Audibert would have looked at what he thought he needed to look at. I don't exactly know what that is but he would have made an assessment of the registerability of the product.

"QUESTION: Do you know if he, in fact, looked at any materials?

"ANSWER: I really don't know all of what he looked at. I mean --

"QUESTION: Aside from Mr. Audibert, do you know of anybody else in global marketing who worked on this matter?

"ANSWER: No. He may have, let me just add, he may have asked for some help from market research or some of the other feeding areas but I don't know.

"QUESTION: You don't know who he asked?

"ANSWER: I don't but it doesn't mean he didn't.

"QUESTION: You have no knowledge if he asked anybody else?

"ANSWER: I have no knowledge."

MR. GINSBURG: Page 58, line 11:

"Let me have marked as Lauda Exhibit 5 a document bearing the numbers SP 1200189 through SP 1200199.

"QUESTION: Mr. Lauda, let me hand you what's been marked as Lauda Exhibit 5 and ask you just to briefly look over that document. Mr. Lauda, have you ever seen this document before?

"ANSWER: No.

"QUESTION: Did you have, to your knowledge, did you have any input in its preparation?

"ANSWER: No.

"QUESTION: To your knowledge did any

person in global marketing have any --

"ANSWER: Excuse me.

"QUESTION: Sure.

"ANSWER: I would say that there was input into it because we did provide a financial and commercial analysis of the project so let me say that we did provide input.

"QUESTION: Aside from your financial and commercial assessments, I believe you talked about those at your last deposition, did you provide any input into this document, to your knowledge?

"ANSWER: No.

"QUESTION: Did you suggest any of the terms in this document to your knowledge?

"ANSWER: No.

"QUESTION: Do you know who did work on this document?

"ANSWER: To the best of my understanding Ray Kapur and Jeff Wasserstein. My only contact with this project was through Ray.

"QUESTION: You had no conversation with Mr. Wasserstein about it?

"ANSWER: None.

"QUESTION: So, you don't know what terms

are contained in that document?

"ANSWER: No."

MR. GINSBURG: Page 71, line 15:

"QUESTION: Did you have a chance to look at the agreement between Upsher-Smith and Schering?

"ANSWER: I did.

"QUESTION: Is there any provision in here that would prevent Upsher-Smith from simply pocketing the money and walking away from the product?

"ANSWER: I didn't see anything in here that would require them to perform."

MR. GINSBURG: Page 82, line 3:

"MR. EISENSTAT: I'd like to have marked as Lauda Exhibit 8 a two-page document bearing the numbers SP 002776 through SP 002777.

"QUESTION: Mr. Lauda, I'd like to hand you what's been marked as Lauda Exhibit 8 and ask you if you would look that over and tell me if you have any recollection of ever having seen that document before. Do you recall ever seeing this before?

"ANSWER: No.

"QUESTION: Let me direct your attention to

the sixth paragraph down, it says, 'The NDA was filed 5/6/96. FDA has completed the medical review and they are currently discussing labeling with Kos.' Do you see that?

"ANSWER: Yes.

"QUESTION: And do you see the upper right-hand corner, the contact date for this memo is March 13th, 1997; do you see that?

"ANSWER: Yes.

"QUESTION: My question to you is would it be unusual for a new drug application to have been filed in May of 1996 and not yet be granted by March of 1997?

"ANSWER: Would it be unusual?

"QUESTION: Yeah.

"ANSWER: Would it be unusual to not be approved?

"QUESTION: Right.

"ANSWER: No, it would be normal for it to be sitting at least eight to twelve months, best case.

"QUESTION: So, this delay doesn't show any delay with the Kos product?

"ANSWER: No.

"QUESTION: If the new drug application had been submitted, would that mean that Kos had completed its phase III clinical trials?

"ANSWER: Yes.

"QUESTION: If the new drug application had been submitted by Kos, would that mean that the Niaspan product was what is sometimes referred to as in late stage development?

"ANSWER: Would it mean that the Niaspan -- I would say yes, it -- yes.

"QUESTION: Do you know when, in fact, Kos was granted its NDA for Niaspan?

"ANSWER: I don't recall. I know they're in the market. I don't know when they -- I think they launched it in '99. I don't recall. I know they're in the market.

"QUESTION: Do you know if Upsher-Smith had filed its NDA by the time Mr. Audibert performed his financial assessment of Niacor-SR?

"ANSWER: They had not, they hadn't concluded their clinical trials."

MR. GINSBURG: Page 112, line 21:

"QUESTION: To your knowledge has Schering ever paid $60 million in up-front payments for

the license to a product without asking to see the correspondence between the company and the FDA on an unapproved product?

"ANSWER: I can't think of one. I'd have to think about that. I can't think of one."

MR. GINSBURG: That's all, Your Honor, we have for Mr. Lauda's deposition.

JUDGE CHAPPELL: Thank you, Mr. Ginsburg.

Anything from Schering?

MR. RAOFIELD: Yes, Your Honor.

JUDGE CHAPPELL: How do you pronounce your name, is it "Raofield"?

MR. RAOFIELD: "Raofield," Your Honor.

JUDGE CHAPPELL: Thank you.

MR. RAOFIELD: Complaint counsel questioning the witness at page 46, line 4:

"QUESTION: You've had a lot of experience with licensing provisions with Schering; is that fair?

"ANSWER: Yes.

"QUESTION: Would you have entered into a contract with Upsher-Smith that paid them $60 million and there was no provision requiring them to continue to work on the product or do anything more on the product or do anything

except put the $60 million in their pocket?"

There was an objection and the court reporter reads the question back beginning on page 46, line 21.

"ANSWER: I think I would have entered into an agreement that gave me certain residual rights and I'd have to sit back and think about how I would approach them in that circumstance, but I think I would have asked for certain residual rights, perhaps the opportunity to do it myself, and I don't know that that was or was not in there. Now -- so does that answer your question?

"QUESTION: Could you explain a little more what you mean by residual rights?

"ANSWER: Well, perhaps I would like to have had the opportunity to say, "Okay, you want to walk away, I have the right to develop it myself and file it myself in the territories agreed to." We've done that.

"QUESTION: Would you have entered into a contract with Upsher-Smith that said Upsher-Smith retains the right to grant another company licenses to our patents involved in this product?

"ANSWER: I would have. That's not -- that

wasn't on my criteria here. The patents were not something we thought were that valuable. What was valuable to us was the opportunity to have a product in a therapeutic area where we were heading full steam ahead with one of our own research products. So, it wasn't the patents that in any way influenced me. I mean, we were assuming this was a generic product with generic technology and that there would be other people in the marketplace."

MR. RAOFIELD: Page 49, line 3:

"QUESTION: Do you know if regulatory affairs was involved in the Upsher-Smith/ Schering license agreement?

"ANSWER: Not that I know of. Jim had them as available to him if he needed them, but I don't know that they were or they weren't.

"QUESTION: Do you know if anybody went back and checked the correspondence between the FDA and Upsher-Smith?

"ANSWER: Not that I know of.

"QUESTION: Don't you think that was something that would have been important to have been done?

"ANSWER: Could have been but -- could have

been but I think in our particular case it wasn't something that was a driving concern, again because of the program we were looking at. It wasn't something we would expect to create a difficult situation, again with a generic product and generic technology. It wasn't something that we would expect to see significant regulatory hurdles, so it would all depend on what Jim felt he needed or didn't know. You have to keep in mind that Jim deals with these things in a global way day in and day out. It's not that he needs to get -- needs to get technical advice on every single issue. If an issue comes up that concerns him, he may ask."

MR. RAOFIELD: Page 51, line 5, complaint counsel questioning the witness:

"QUESTION: Would you be disappointed in your employees if they recommended spending $60 million on licensing a product when no one had checked to see if the PK studies were done and approved?

"ANSWER: I don't think I'd be disappointed. I think I have a confidence in my employees that they have assessed the

overall program, one, you know an area that may be difficult and turned out to be in this case, wasn't a death blow to the product. It was a question of would we want to go on and do it ourselves.

"QUESTION: When you say it wasn't a death blow to the product, what are you talking about?

"ANSWER: Could have been redone. Could have been done.

"QUESTION: Do you know anything about the PK studies?

"ANSWER: In the end, I understand that the PK study would have had to have been redone. It's not that it couldn't have been redone.

"QUESTION: Is that something that Schering would have the ability to help in?

"ANSWER: Yes."

MR. RAOFIELD: Again, Your Honor, this is an area where I need to read a few lines of complaint counsel's designation to place in context the counter-designation.

JUDGE CHAPPELL: Okay.

MR. RAOFIELD: Complaint counsel's designation, page 71, line 15, complaint counsel questioning the

witness:

"QUESTION: Did you have a chance to look at the agreement between Upsher-Smith and Schering?

"ANSWER: I did.

"QUESTION: Is there any provision in here that would prevent Upsher-Smith from simply pocketing the money and walking away from the product?

"ANSWER: I didn't see anything in here that would require them to perform."

MR. RAOFIELD: At this point, Your Honor, there was an objection, and Schering's counter-designation is the continuation of the answer.

"ANSWER: Okay, and I think it's important to say I have no -- to restate that I have not seen this document before today, and I think it's also on issue to say I'm not a lawyer, and I don't know what -- what were in the heads and the mind of the people sitting around the table crafting this, but in reading it, I don't see anything in here that would specifically require them to perform in terms of providing us with a registration. I do, however, see clauses in here that allow us to

stand in their shoes in the sense that they should -- they are -- it seems to me that they would have to give us all intellectual property and we then could make the decision to proceed ahead. That's not uncommon, I just want to say that that's not an uncommon situation, and in fact some of those -- some of these contracts that -- these deals that we've looked at have similar type arrangements wherein a party can decide not to move ahead; however, the other party would be entitled to do it themselves or to gain access to all of the -- all of the data. So it's not an entirely unusual situation."

MR. RAOFIELD: That concludes Schering's counter-designations, Your Honor.

JUDGE CHAPPELL: Thank you.

MR. CARNEY: Upsher-Smith's designations fall within those read by Schering-Plough, so we have nothing to add at this time.

JUDGE CHAPPELL: Okay.

MS. BOKAT: Your Honor, our next readings would be from the investigational hearing of James Audibert. I just wanted to alert the Court that they are lengthy, and we would probably go beyond 5:30. We are certainly

willing to proceed. I just didn't want to create any unfairness.

JUDGE CHAPPELL: How many more readings do we have?

MS. BOKAT: We have -- pardon me, readings from Mr. Audibert's investigational hearing and from his deposition.

JUDGE CHAPPELL: That's all?

MS. BOKAT: Yes, Your Honor.

JUDGE CHAPPELL: That's all the deposition transcript excerpts we're going to have?

MS. BOKAT: It is, Your Honor.

JUDGE CHAPPELL: Okay. Are you -- and you're reading from his investigational hearing transcript as well as his deposition?

MS. BOKAT: That is correct.

JUDGE CHAPPELL: How long do you think it will take to go through the investigational hearing transcript portion?

MS. BOKAT: May I confer with my colleagues?

JUDGE CHAPPELL: Yes, you may.

MS. BOKAT: Thank you.

(Counsel conferring.)

MS. BOKAT: Our best estimate is that our readings from the investigational hearing transcript

would be approximately 18 minutes.

MR. RAOFIELD: Having looked at it quickly, Your Honor, my guess would be that our counter-designations would be about eight minutes.

MR. CARNEY: We would need an additional three minutes, Your Honor.

JUDGE CHAPPELL: Okay, so we could at least knock out the investigational hearing transcript portion. Why don't we proceed with that, then.

MS. BOKAT: Okay.

JUDGE CHAPPELL: Off the record.

(Discussion off the record.)

JUDGE CHAPPELL: Back on the record.

MS. BOKAT: So, these readings take up with James Audibert from his investigational hearing transcript. That hearing was conducted September 21st in the year 2000.

JUDGE CHAPPELL: And his title or position?

MS. BOKAT: He was an employee of Schering-Plough. I believe he worked in global marketing.

MR. NIELDS: He was senior director of the -- I'm going to get this close but not perfect, Your Honor -- cardiovascular and central nervous system group in global marketing.

JUDGE CHAPPELL: Is he still in the same position?

MR. NIELDS: No, he is now in the R&D section.

MS. SHORES: Schering-Plough Research Institute is the name of Schering's R&D department.

JUDGE CHAPPELL: Okay, thank you.

You may proceed.

MR. GINSBURG: Thank you.

Page 24, line 4:

"QUESTION: Did you have any meetings ever with Upsher-Smith about the Upsher-Smith niacin product Niacor-SR?

"ANSWER: No.

"QUESTION: You never went to their office to meet with them?

"ANSWER: No."

MR. GINSBURG: Page 32, line 3.

"QUESTION: Do you have any general recollection of what you were asked to do?

"ANSWER: Yes. I was asked to develop a sales forecast for this particular product.

"QUESTION: Anything beyond a sales forecast?

"ANSWER: I think at one point actually do what we call a profit and loss, a P&L."

MR. GINSBURG: Page 39, line 22:

"MR. EISENSTAT: I'd like to have marked as Audibert Exhibit 1 an eight-page document bearing the numbers for identification SP 16000040 through SP 1600047.

"QUESTION: Mr. Audibert, you've been handed what's been marked as Audibert Exhibit 1. I'd ask you to look over this document and tell me if you recognize what this document is.

"ANSWER: Yes.

"QUESTION: What is the document?

"ANSWER: It's a document that I prepared for Mr. Lauda.

"QUESTION: Is this your assessment of the Upsher-Smith niacin product Niacor-SR?

"ANSWER: Yes."

MR. GINSBURG: Page 41, line 15:

"MR. EISENSTAT: I'd like to have marked as the next Audibert exhibit in order Audibert Exhibit 2, a 52-page document bearing the numbers for identification SP 1600061 through SP 1600112.

"QUESTION: I'd ask you, Mr. Audibert, to look at what's been marked as Exhibit 2 and

tell me if you recognize what that document is.

"ANSWER: It's a document that was supplied to me as a part of my assessment of the product.

"QUESTION: And when you say 'the product,' you're talking about the Upsher-Smith niacin product Niacor-SR?

"ANSWER: Yes.

"QUESTION: Do you recall who supplied the document to you?

"ANSWER: No.

"QUESTION: I direct your attention to the top of the first page of the document. There's what appears to be a facsimile transmission line here and in the center it says, 'Warrick Pharm.' Do you see that?

"ANSWER: Yes.

"QUESTION: Does that refresh your recollection at all about how you came to have possession of this document?

"ANSWER: No.

"QUESTION: Do you recall at all being sent documents by Ray Kapur regarding the Upsher-Smith niacin product Niacor-SR?

"ANSWER: No.

"QUESTION: Do you recall being sent documents by anybody from Warrick Pharmaceuticals about the Upsher-Smith niacin product Niacor-SR?

"ANSWER: No."

MR. GINSBURG: Page 43, line 23:

"QUESTION: Still looking at Exhibit 2 and the fax transmission line at the top -- it's a little clearer if you turn to the back to some of the pages -- it's clear that this document was faxed on June 12, 1997. Do you see that?

"ANSWER: I see the information, but I don't know what that information means.

"QUESTION: Well, do you see the first -- the very first entry on that top fax line, 6-12-97?

"ANSWER: Yes.

"QUESTION: Is it your understanding that that means June 12, 1997?

"ANSWER: Yes.

"QUESTION: Does that refresh your recollection at all with respect to when you started working on the assessment of the Upsher-Smith niacin product Niacor-SR?

"ANSWER: No.

"QUESTION: Could you have done your assessment of the Upsher-Smith niacin product Niacor-SR without the kind of information that was in this document?

"ANSWER: No.

"QUESTION: Do you know if you had any other source for that information except this document?

"ANSWER: No, I did not have any."

MR. GINSBURG: Page 52, line 10:

"QUESTION: Do you recall getting assistance from anybody in doing your assessment of the Upsher-Smith niacin product Niacor-SR?

"ANSWER: No."

MR. GINSBURG: Page 71, line 10:

"QUESTION: In the second bullet point where it says, 'In spite of this unique profile, niacin has not been widely used for the treatment of elevated cholesterol for the following reasons,' and the second bullet point is, 'Previously developed sustained-release products were associated with hepatotoxicity.'

"Do you see that?

"ANSWER: Yes.

"QUESTION: Did you write that?

"ANSWER: Yes.

"QUESTION: For the record, could you explain what hepatotoxicity is?

"ANSWER: Hepatotoxicity is liver damage.

"QUESTION: Why would the fact that previously developed sustained-release niacin products were associated with hepatotoxicity be a reason that niacin would not be widely used for the treatment of elevated cholesterol?

"ANSWER: Because if the product did cause a certain incidence of hepatotoxicity, then patients and physicians would be less likely to use it."

MR. GINSBURG: Page 75, line 9:

"QUESTION: Going back to Exhibit 1, the third bullet point in the section we've been talking about on SP 1600042 says, 'None of the SR products are indicated for the treatment of hypercholesterolemia.'

"Do you see that line?

"ANSWER: Yes.

"QUESTION: Did you write that?

"ANSWER: Yes.

"QUESTION: First of all, what does it mean for a product to be indicated for the treatment of a condition?

"ANSWER: It means that it has regulatory approval for that particular indication.

"QUESTION: In the United States, how do you get that regulatory approval?

"ANSWER: Through the Food and Drug Administration."

MR. GINSBURG: Page 93, line 13:

"QUESTION: Do you know where Upsher-Smith stood with respect to European regulatory submissions?

"ANSWER: I don't believe they had done -- they were not going to do it.

"QUESTION: They were not going to make European regulatory submissions?

"ANSWER: I believe we were going to do the regulatory submissions.

"QUESTION: When you say 'we,' that would be Schering was planning to do the European regulatory submissions for the Upsher-Smith niacin product Niacor-SR?

"ANSWER: That's correct.

"QUESTION: Do you know if Schering ever made those regulatory submissions?

"ANSWER: I'm not aware of that we did.

"QUESTION: Do you know why not?

"ANSWER: The main reason, we didn't have an NDA to work off of.

"QUESTION: Why would you want an NDA to work off of?

"ANSWER: Because how we often prepare our European dossiers is we take the NDA as the baseline document, document in a broad sense here, and make some adjustments that have to be done for peculiarities to the European health authorities and then submit the dossier.

"But the contents of the NDA serves as the large foundation of your European filing.

"QUESTION: Is that a requirement in the European filing?

"ANSWER: I'm sorry. Is what a requirement?

"QUESTION: That you use the NDA as the foundation.

"ANSWER: No.

"QUESTION: So, Schering was permitted under the European regulations to simply create their own dossier and submit it for approval in Europe. Is that right?

"ANSWER: Yes.

"QUESTION: Was that done?

"ANSWER: Not that I'm aware of.

"QUESTION: Do you know why not?

"ANSWER: Because we did not have an NDA to work off of.

"QUESTION: Well, why didn't you just create your own dossier without an NDA?

"ANSWER: I don't know the exact reason why that occurred, but I do know creating a document without an NDA to work off of is a very resource-intensive and time-intensive process.

"QUESTION: Do you have a sense of how resource-intensive and how time-intensive it is?

"ANSWER: No, I don't have a specific...

"QUESTION: Do you have any kind of ballpark feel for what it would cost to put together a dossier for European regulatory authorities if you didn't have an NDA to work

from?

"ANSWER: No, I do not."

MR. GINSBURG: Page 120, line 25:

"QUESTION: Do you recall global marketing being assigned the responsibility for getting regulatory approval for the Niacor-SR product in Europe?

"ANSWER: No, I do not.

"MR. EISENSTAT: I'd like to have marked as the next Audibert exhibit in order, Exhibit 6, a one-page document bearing the number SP 1600237.

"QUESTION: Mr. Audibert, you've been handed Exhibit 6. If you could look that over and tell me if you recognize the document.

"ANSWER: Yes, I recognize it.

"QUESTION: What is the document?

"ANSWER: It's a document from -- to Tom Lauda from Mr. Kapur discussing what activity he would like global marketing to do to keep him apprised of the development status of the product.

"QUESTION: There's a handwritten note on the document at the top. Do you see that?

"ANSWER: Yes.

"QUESTION: Does it say, 'To Jim Audibert. Please see me urgently. Tom'? Is that what it says?

"ANSWER: Yes."

MR. GINSBURG: Page 122, line 22:

"QUESTION: Okay. The second sentence of the note from Mr. Kapur to Mr. Lauda says, 'Although global marketing is fully responsible for developing and registering Niacor-SR, please instruct your designated project leader to set up a quarterly briefing for me on the development status so that I can update Ian Troup, president of Upsher-Smith, regarding timely progress towards registration and keep our relationship with Upsher on track.'

"Do you see that?

"ANSWER: Yes.

"QUESTION: Did you have an understanding that global marketing was fully responsible for developing and registering Niacor-SR?

"ANSWER: I don't -- I don't remember what I thought when I saw this.

"QUESTION: Well, now, do you recall that you had -- that global marketing was fully

responsible for developing and registering Niacor-SR?

"ANSWER: Global marketing is not responsible for registering products, so as I read it today, this is what's confusing.

"QUESTION: You just don't understand what this means?

"ANSWER: That's correct.

"QUESTION: Did you have a designated project leader, to your knowledge, for the Niacor-SR?

"ANSWER: I'm not sure of whether he meant me, but I'm not sure there was a designated project leader.

"QUESTION: I'm not sure I understood your answer. Do you know if there was any designated project leader in global marketing for this product?

"ANSWER: Well, I don't know what Mr. Kapur means by the term 'designated project leader.'

"QUESTION: Okay. Did you consider yourself a designated project leader for Niacor-SR?

"ANSWER: I guess de facto.

"QUESTION: Did you set up a quarterly

briefing for Mr. Kapur on the development status of Niacor-SR?

"ANSWER: Not formal. I don't remember setting up quarterly briefing meetings with Mr. Kapur, but again, as I previously mentioned, I did talk to him periodically."

MR. GINSBURG: Page 124, line 18:

"MR. EISENSTAT: I'd like to have marked as the next Audibert exhibit in order, Audibert Exhibit 7, a one-page document bearing the number SP 1800004.

"QUESTION: Before we get to Exhibit 7, did you feel that you were responsible for development and registration work on Niacor-SR?

"ANSWER: No.

"QUESTION: Did you feel anybody else in global marketing was responsible for development and registration work on Niacor-SR?

"ANSWER: No."

MR. GINSBURG: Page 127, line 12:

"QUESTION: Well, you were -- it seems like you were given instructions to do some international registration which you didn't

do.

"What did you do when you got these?

"ANSWER: I don't remember specifically what I did when I got this.

"QUESTION: But whatever it was, whatever you did, it was not working on the international registration and marketing of Niacor-SR?

"ANSWER: That's -- that's true."

MR. GINSBURG: Page 133, line 5:

"MR. EISENSTAT: I'd like to have marked as the next Audibert exhibit in order Audibert Exhibit 10, a one-page document bearing the number SP 1600236.

"QUESTION: And once again, if you would look over this document and tell me if you recognize it.

"ANSWER: Okay.

"QUESTION: Do you recognize this document?

"ANSWER: Yes.

"QUESTION: And what is the document?

"ANSWER: It's a document I sent to Mr. Kapur, updating him on the status of Niacor-SR.

"QUESTION: And in this document you

recount a conversation you had with Mark Halvorsen; is that right?

"ANSWER: Yes."

MR. GINSBURG: Page 134, line 5:

"QUESTION: Okay, so as of this date, you'd been unable to arrange for Upsher-Smith to give you access to the documents you were interested in seeing with respect to the regulatory clinical document; is that right?

"ANSWER: Yes."

MR. GINSBURG: Page 135, line 18:

"MR. EISENSTAT: I'd like to have marked as the next Audibert exhibit in order, Exhibit Number 11, a two-page document bearing the number SP 0500013 through SP 0500014.

"QUESTION: And once more, Mr. Audibert, if you would look over Exhibit 11 and tell me if you recognize the document.

"ANSWER: I vaguely recognize it.

"QUESTION: And what is the document?

"ANSWER: Well, the top page is a memo from Mr. Kapur to myself referring to discussions he had with Ian Troup at the NWDA meeting and he describes -- he discussed his October 22 fax.

"QUESTION: And what's the NWDA meeting?

"ANSWER: I don't know.

"QUESTION: You don't know what NWDA stands for?

"ANSWER: No.

"QUESTION: Do you recall after receiving this whether or not you got the health registration dossier sent to you in segments with information in a format that would enable you to make an evaluation?

"ANSWER: I do not recall receiving that information.

"QUESTION: As I was going through the documents that were produced from your file, I get to this document and then there's no more mention in your files of the Upsher-Smith niacin product in 1997.

"Do you recall if you did anything else?

"ANSWER: I don't recall a specific -- I might have, but I just don't recall."

MR. GINSBURG: Page 137, line 8:

"QUESTION: Upsher-Smith's original schedule as shown in Exhibit 2 was to have their FDA filing at the end of 1997. Do you recall that?

"ANSWER: Yes.

"QUESTION: Did they make that date?

"ANSWER: Not that I'm aware.

"QUESTION: When they failed to make that date, do you recall if you did anything?

"ANSWER: I don't recall."

MR. GINSBURG: Page 137, line 23:

"QUESTION: At some point, Upsher-Smith told Schering that they weren't going to proceed any further on Niacor-SR; is that right?

"ANSWER: That's correct.

"QUESTION: Do you recall approximately when that was?

"ANSWER: I believe it was sometime in 1998.

"QUESTION: You don't have any other recollection as to the timing?

"ANSWER: I believe it was around September."

MR. GINSBURG: Page 140, line 14:

"MR. EISENSTAT: I'd like to have marked as the next Audibert exhibit in order, Exhibit 14, a two-page document bearing the numbers SP 1600057 through SP 1600058.

"QUESTION: And Mr. Audibert, would you look at Exhibit 14 and tell me if you recognize this document.

"ANSWER: Yes, I recognize it.

"QUESTION: And what is the document?

"ANSWER: It's a memo to Mr. Lauda from myself, updating him on a conversation that Mr. Kapur and I had had with Mr. Troup of Upsher-Smith.

"QUESTION: Was this the conversation where Mr. Troup finally told you that they weren't going to proceed on their niacin product Niacor-SR?

"ANSWER: I believe so. I...

"QUESTION: When you were told by Mr. Troup that they weren't, Upsher-Smith weren't going to go ahead with Niacor-SR, did it ever occur to you to go ahead on your own, that is, Schering go ahead and get the registration for Niacor-SR in Europe themselves?

"MS. SHORES: Did it ever occur to Schering?

"MR. EISENSTAT: Did it ever occur to him.

"MS. SHORES: Oh, okay. I thought you said to Schering.

"THE WITNESS: Not that I can recollect."

MR. GINSBURG: Thank you, Your Honor, that's all we have for Mr. Audibert's investigational hearing.

JUDGE CHAPPELL: Schering?

MR. RAOFIELD: Page 37, line 14, complaint counsel questioning the witness --

JUDGE CHAPPELL: Hold on, just a second, Mr. Raofield.

Ms. Bokat, the deposition transcript excerpts of Mr. Rosenthal, were those combined into a complaint counsel exhibit?

MS. BOKAT: They were, Your Honor, and we put an exhibit number on them.

JUDGE CHAPPELL: All right, I didn't want to let that slip by. I'd like to have that marked for identification and given to the court reporter before we conclude today, if you have a copy.

MS. BOKAT: I should have it here. I will look for it while the proceedings continue, if that's acceptable.

JUDGE CHAPPELL: Okay, thank you, great.

Sorry, you may proceed.

MR. RAOFIELD: Absolutely, Your Honor.

Page 37, line 14, complaint counsel questioning the witness:

"QUESTION: Do you recall what information you used to do your assessment of the Upsher-Smith niacin product Niacor-SR?

"ANSWER: Vaguely.

"QUESTION: Well, what do you recall about that?

"ANSWER: As I had previously mentioned, we had been doing a substantial amount of work in understanding the current cholesterol market on a worldwide basis, because we have a product in development, ezetimibe, and so as a part of that -- of those activities, we were looking at what was the current market size, what type of products composed what percentage of the market, what type of market growth was expected, where did that growth come from, what were the trends in treating hypercholesterol, were there any new guidelines coming out. I mean, we had a very active program in place to very thoroughly understand the cholesterol market, both current and future.

MR. RAOFIELD: Page 45, line 15, complaint counsel questioning the witness:

"QUESTION: Do you recall if you had any

other information from Upsher-Smith or that originated with Upsher-Smith about their niacin product Niacor-SR?

"ANSWER: I know I also received some protocol information, but I don't remember exactly when that was."

MR. RAOFIELD: Page 76, line 20, complaint counsel questioning the witness:

"QUESTION: In determining your assessment of the value of a license for the Upsher-Smith niacin product, Niacor-SR, was one of the factors you considered whether or not Upsher-Smith was going to get an indication for the treatment of hypercholesterolemia?

"ANSWER: Yes.

"QUESTION: And how did that factor into your assessment?

"ANSWER: Well, if a product did not have that indication, then in many cases it may not be reimbursed by a particular health authority or some insurance company or what have you, and we also can't promote it for that indication.

"QUESTION: Would that adversely affect the sales of the product?

"ANSWER: Yes.

"QUESTION: Did you -- when you were doing your assessment, did Upsher-Smith have an indication for the niacin product Niacor-SR for the treatment of hypercholesterolemia in any jurisdiction?

"ANSWER: Not that I am aware of.

"QUESTION: In reaching your assessment, did you expect that they would get that indication?

"ANSWER: Yes."

MR. RAOFIELD: Page 127, line 22, complaint counsel questioning the witness:

"MR. EISENSTAT: I'd like to have marked as the next Audibert exhibit in order, Audibert Exhibit 8, a two-page document bearing the number SP 0500022 through SP 0500023.

"QUESTION: Mr. Audibert, you've been handed what's been marked as Exhibit 8, and once again, I'd like to ask you to look over this document and see if you can recognize it.

"ANSWER: Yes, I recognize it.

"QUESTION: And what is the document?

"ANSWER: It's -- the cover memo is a memo to Mr. Ian Troup of Upsher-Smith from Mr.

Kapur regarding a GMP visit, and attached to that memo is a letter from Mr. Ian Troup -- to Mr. Ian Troup from Ray Kapur regarding activities.

"QUESTION: First of all, what's a GMP visit?

"ANSWER: I know what GMP stands for, but I don't know exactly what a GMP visit is.

"QUESTION: What does GMP stand for?

"ANSWER: GMP is good manufacturing practices.

"QUESTION: The second paragraph of the letter on page SP 0500023 reads, 'I have also given Jim Audibert, directing of marketing in international, Mark Halvorsen's name as the contact person for regulatory to schedule a visit to discuss the Niacor-SR submission.'

"Do you see that paragraph?

"ANSWER: Yes.

"QUESTION: Do you recall that happening?

"ANSWER: What happening?

"QUESTION: That Mr. Kapur gave you Mark Halvorsen's name as a contact person for regulatory to schedule a visit to discuss the Niacor-SR submission.

"ANSWER: I vaguely remember that, yeah.

"QUESTION: Were you director of marketing international at that time?

"ANSWER: No.

"QUESTION: What was your title at that time?

"ANSWER: Senior director of global marketing.

"QUESTION: Did you contact Mr. Halvorsen?

"ANSWER: Yes.

"QUESTION: What did you -- what do you recall about contacting Mark Halvorsen?

"ANSWER: My recollection is that I tried to set up a meeting to go out there to review the materials, but the materials were not in a format that would allow us to review them.

"QUESTION: Okay. And why were you looking to review the materials?

"ANSWER: Because I was coordinating with our regulatory people to have -- as I mentioned before, the whole process behind this was to have Upsher-Smith do the NDA. We would then take the NDA, make the necessary changes, and submit it to the European health authorities.

"QUESTION: And you were coordinating with -- and you were coordinating this with your regulatory people?

"ANSWER: Well, I was asked to coordinate that through Upsher-Smith.

"QUESTION: Which of your regulatory people were working on it, do you recall?

"ANSWER: I was talking to this with the head of our regulatory division in Europe.

"QUESTION: And who was that?

"ANSWER: His name is John Pierre Osselaere."

MR. RAOFIELD: Page 134, line 10:

"QUESTION: The middle paragraph, the last line says, 'Mark has provided me with the Niacor protocols, and these have been forwarded to SPRI. Do you see that?

"ANSWER: Yes.

"QUESTION: What's SPRI?

"ANSWER: Schering-Plough Research Institute.

"QUESTION: Okay. The last line says that you will update Mr. Kapur after you speak with Mark on September 2. Do you recall if you continued to call Mr. Halvorsen and to try to

get this information?

"ANSWER: I recall talking with him, but I don't -- I don't know whether it was around September 2nd."

MR. RAOFIELD: Page 136. Your Honor, at this point there are two segments designated by complaint counsel, and Schering has designated two segments between those, and in order for context I'm just going to read all four segments continuously, if that's okay with Your Honor.

JUDGE CHAPPELL: Okay, thank you.

MR. RAOFIELD: Page 136, line 19, complaint counsel questioning the witness:

"QUESTION: As I was going through the documents that were produced from your file, I got to this document, and then there's no more mention in your files of the Upsher-Smith niacin Niacor-SR product in 1997. Do you recall if you did anything else?

"ANSWER: I don't recall a specific -- I might have, but I just don't recall.

"QUESTION: Do you recall giving up on the product?

"ANSWER: No.

"QUESTION: Do you recall making any

efforts to get the information you wanted from Upsher-Smith?

"ANSWER: As I mentioned before, I had numerous discussions with Upsher-Smith after my initial assessment. I don't remember exactly when those were.

"QUESTION: Upsher-Smith's original schedule as shown in Exhibit 2 was to have their FDA filing at the end of 1997. Do you recall that?

"ANSWER: Yes.

"QUESTION: Did they make that date?

"ANSWER: Not that I'm aware of.

"QUESTION: When they failed to make that date, do you recall if you did anything?

"ANSWER: I don't recall.

"QUESTION: Did you ever, when you were making these numerous discussions with Upsher-Smith, did you ever get the feeling that Upsher-Smith was being less than honest with Schering with regard to Niacor-SR product?

"ANSWER: No."

MR. RAOFIELD: Page 140, line 14, complaint counsel questioning the witness:

"MR. EISENSTAT: I'd like to have marked as the next Audibert exhibit in order, Exhibit 14, a two-page document bearing the numbers SP 1600057 through SP 1600058.

"QUESTION: Mr. Audibert, would you look at Exhibit 14 and tell me if you recognize this document?

"ANSWER: Yes, I recognize it.

"QUESTION: And what is the document?

"ANSWER: It's a memo to Mr. Lauda from myself updating him on a conversation that Mr. Kapur and I had with Mr. Troup of Upsher-Smith.

"QUESTION: Was this the conversation where Mr. Troup finally told you that they weren't going to proceed on their niacin product Niacor-SR?

"ANSWER: I believe so. I...

"QUESTION: When you were told by Mr. Troup that they weren't, Upsher-Smith weren't going to go ahead with Niacor-SR, did it ever occur to you to go ahead on your own, that is, Schering to go ahead and get the registration for Niacor-SR in Europe themselves?"

There's an objection, and the witness

answers.

"ANSWER: Not that I can recollect.

"QUESTION: If we look back on Exhibit 1, you had a sales estimate for a Niacor-SR product in Europe, and you recall we talked earlier about your sales estimate for that. Do you recall that?

"ANSWER: Yes.

"QUESTION: If in September of 1998 Schering had obtained a registration or dossier approval for Niacor-SR in Europe on its own, would you still have been able to achieve that same sales projection?

"ANSWER: It's hard to say.

"QUESTION: Why is it hard to say?

"ANSWER: Well, it's hypothetical.

"QUESTION: Would anything have changed between the time you did your sales projection in 1997 through September of 1998 that would make you think that your sales projection could not have been achieved for the Niacor-SR product?

"ANSWER: Well, I think that a significant factor was what I saw, and as I reflected in the memo, the rather poor uptake of the Kos

product in the United States.

"QUESTION: So, you were projecting that with Kos' experience in the United States, you would expect that your sales projection in Europe would not likely be made?

"ANSWER: It would be more difficult. I know Kos put a significant amount of effort behind the product. They had some substantial expectations of the sales potential, and this was their real life test of that hypothesis, and unfortunately, for a number of different reasons, and I'm not aware of all of them, but for a number of different reasons, the product did not do well in the marketplace."

MR. RAOFIELD: Page 144, line 6, complaint counsel questioning the witness:

"QUESTION: Just a few other questions. To your knowledge, at any time, did Schering begin to put together any kind of marketing plan for Niacor-SR in Europe?

"ANSWER: No. I think the reason that occurred is we usually start to put together those marketing plans when we submit an HRD.

"QUESTION: When you submit a what?

"ANSWER: An HRD, a health registration

dossier, and at that point you're wondering had Carol -- you know, you saw that document, that note that said have Caroline work on a plan. I don't remember which one that said. The timing of that is usually on or about the time we submit our HRD, and the reason being it is just because of the number of activities we have ongoing when you -- when you submit your HRD, you have at that point in time a definitive picture of the product's profile, what the anticipated registration claim is, and what have you, and the good reason we don't start -- often do not start earlier is exactly this. Had we started when I think Tom wrote me that note, I forget when that exact date was, we would have been working on a marketing plan for a year for a product that never came to be. July -- yeah, July 1997. So, no, we did not write a marketing plan, and that's -- again, we usually wait and do that around the time of the filing."

MR. RAOFIELD: Page 150, line 22, complaint counsel questioning the witness:

"QUESTION: Okay, when you -- just to go over the dates again, you assumed that

Upsher-Smith would file their NDA at the end of 1997. Is that right?

"ANSWER: Yes.

"QUESTION: And then how long would you have expected it to take for your people to turn their NDA into the appropriate dossier for Europe?

"ANSWER: Not very long.

"QUESTION: Are we talking months or years?

"ANSWER: Oh, no, no, not even a month. Again, the way this process works is we don't have to wait until they have the final NDA. Basically, as they start to package it, we would then start to get the pieces and start the reformatting. So, if we do this ourselves, it's not uncommon for us to actually be filing our NDA and HRD simultaneously. Even though the NDA is the lead document, the people assembling the HRD start getting -- as it starts to get put together, they start working on the HRD, so it can be very quickly. It can be, if not simultaneously, in a matter of weeks you can file your HRD as compared to NDA."

MR. RAOFIELD: Your Honor, that concludes

Schering's counter-designations for the investigational hearing of Mr. Audibert.

JUDGE CHAPPELL: Thank you.

Anything from Upsher?

MR. CARNEY: Yes, Your Honor. Most all of Upsher's designations fall within those read by Schering, with the exception of one. It begins at page 74, line 6. To put it in context, this is referring to the Niacor 115 study.

"QUESTION: Do you have in your mind a level at which people could show up as being prematurely discontinued from the study due to one of these liver events that would cause you concern that people wouldn't want to take the product because of the possibility of liver damage?

"ANSWER: I did not have a specific number in mind.

"QUESTION: Looking at these numbers, are these numbers at all troubling?

"ANSWER: The highest dose is starting to get up there. Three and seven are not troubling.

"QUESTION: That is the highest dose, column D?

"ANSWER: That's correct.

"QUESTION: And 16 percent of the people who were on the column D were discontinued from the study because of an adverse event relating to one of these liver functions?

"ANSWER: That's what the chart shows, yes.

"QUESTION: And that's starting to get up to a level that would be troubling?

"ANSWER: Well, it's not a level itself. In all of these assessments, what you have to look at is the total information you look at, but here what you see here is not surprising as a dose-related increase in side effects, and for a drug like niacin, that's not surprising at all.

"QUESTION: That's well known?

"ANSWER: Oh, yes."

MR. CARNEY: That's all, Your Honor, for Upsher-Smith.

JUDGE CHAPPELL: Ms. Bokat, as I thought about it, hold off on that exhibit that we talked about, which are the transcript designations from Mr. Rosenthal, because it occurred to me if we make it an exhibit, it may become part of the public record, and I'm not sure we want to go that way yet. So, hang onto

it for now.

MS. BOKAT: We will do that, Your Honor.

JUDGE CHAPPELL: We will decide what to do with it next week.

MS. BOKAT: Fine.

JUDGE CHAPPELL: Monday is the 4th, and that's our workday, isn't it? Had we decided that?

MR. NIELDS: Yes, Your Honor.

JUDGE CHAPPELL: So -- and Ms. Bokat, you will -- you have another live witness -- I know we have the cross exam of Dr. Levy, but you have a Mr. Hoffman?

MS. BOKAT: Yes, Your Honor.

JUDGE CHAPPELL: Will he be prepared to go Tuesday if the examination of Dr. Levy is finished?

MS. BOKAT: I've asked my team to have Mr. Hoffman here at 9:30 on Tuesday morning, and if -- if that's all right, he will be sitting through Dr. Levy and then be prepared to go on if Dr. -- if the cross and redirect of Dr. Levy finish in the course of the day on Tuesday.

JUDGE CHAPPELL: Okay, and then we still have to wrap up the deposition excerpt readings. We have one left, right?

MS. BOKAT: That is correct.

JUDGE CHAPPELL: Well, with that, everyone have

a good weekend, and we'll go -- we'll reconvene on Tuesday, February 5th at 9:30 a.m. We're in recess.

(Whereupon, at 5:40 p.m., the hearing was adjourned.)

C E R T I F I C A T I O N O F R E P O R T E R

DOCKET/FILE NUMBER: 9297

CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH

DATE: FEBRUARY 1, 2002

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: 2/4/02

SUSANNE BERGLING, RMR

C E R T I F I C A T I O N O F P R O O F R E A D E R

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

DIANE QUADE